UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION	
This document relates to:	MDL No. 2804
The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al., Case No. 18-op-45090	Hon. Dan Aaron Polster
The County of Cuyahoga, Ohio, et al. v. Purdue Pharma L.P., et al., Case No. 17-op-5004	

CORRECTED AND RESTATED EXPERT REPORT OF KEVIN M. MURPHY, Ph.D.

June 21, 2019

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I. CREDENTIALS

1. My name is Kevin M. Murphy. I am the George J. Stigler Distinguished Service Professor of Economics in the Booth School of Business and the Department of Economics at The University of Chicago, where I have taught since 1983.

2. I earned a doctorate degree in economics from The University of Chicago in 1986. I received my bachelor's degree, also in economics, from the University of California, Los Angeles, in 1981.

3. At The University of Chicago, I teach economics in both the Booth School of Business and the Department of Economics. I teach graduate level courses in microeconomics, price theory, empirical labor economics, and sports analytics. In these courses, I cover a wide range of topics, including the incentives that motivate firms and individuals, the operation of markets, the determinants of market prices, and the impacts of regulation and the legal system. Most of my teaching focuses on two things: how to use the tools of economics to understand the behavior of individuals, firms and markets and how to apply economic analysis to data. My focus in both research and teaching has been on integrating economic principles and empirical analysis.

4. I have authored or co-authored more than 65 articles in a variety of areas in economics. Those articles have been published in leading scholarly and professional journals, including the American Economic Review, the Journal of Law and Economics, and the Journal of Political Economy. I have published in the area of health economics, and was co-

editor of a book discussing the gains from medical research.[1] I have also published articles discussing the economics of addiction and articles discussing the markets for illicit goods.

5. I am a Fellow of the Econometric Society and a member of the American Academy of Arts and Sciences. In 1997, I was awarded the John Bates Clark Medal, which the American Economic Association awarded once every two years to an outstanding American economist under the age of forty. In 2005, I was named a MacArthur Fellow, an award that provides a five-year fellowship to individuals who show exceptional merit and promise for continued and enhanced creative work. In 2007, my colleague Robert Topel and I won the Kenneth J. Arrow Award, which is given annually by the International Health Economics Association for the best research paper in health economics.

6. In addition to my position at The University of Chicago, I am also a Senior Consultant to Charles River Associates ("CRA"), a consulting firm that specializes in the application of economics to law and regulatory matters. I have consulted on a variety of intellectual property, antitrust, fraud, and other matters involving economic and legal issues, such as damages, class certification, labor practices, exclusionary access, tying, mergers, price fixing, price discrimination, and joint ventures.

7. I have submitted testimony in Federal Court, the U.S. Senate, and to state regulatory bodies, and I have submitted expert reports in numerous cases. I have testified on behalf of the U.S. Federal Trade Commission and I have consulted for the U.S. Department of Justice. A list of the testimony I have given over the past four years is provided in my CV, attached as Appendix A. CRA charges $1,400 per hour for my time spent on this matter, and

[1] Murphy, Kevin M., and Robert H. Topel, *Measuring the Gains from Medical Research: An Economic Approach,* University of Chicago Press, 2003.

I receive other compensation from CRA as well. My compensation and the compensation to CRA do not depend on the outcome of this matter.

8. My opinions are based on the information available to me as of the date of this report. The materials that I have relied upon in forming the opinions I offer in this report are identified in Appendix B. My work is ongoing, and I will continue to collect data and other information relevant to the issues and opinions that I discuss in this report. I will review, evaluate, and analyze any relevant material that becomes available to me, and I will supplement my report as necessary to reflect this information. I reserve the right to supplement my opinions based on any additional information obtained that I may be asked to consider, or any additional work or analysis that I may be asked to perform prior to or at any hearing, including deposition or trial. Such additional information includes, without limitation, testimony of Plaintiffs' expert witness Mr. McCann, which was not completed in time to be considered for the purposes of this report. I may supplement and update this report as appropriate based on the results of review procedures and/or additional information that may become available. If asked to offer testimony at trial, I may use documents produced in this litigation that refer to or relate to the matters discussed in my report as exhibits. In addition, I respectfully reserve the right to use animations, demonstratives, enlargements, or any other enhancement in kind of the tables or graphs presented in my report or other information that illustrate my opinions.

II. ASSIGNMENT AND SUMMARY OF CONCLUSIONS

A. Assignment

9. The counties of Summit, Ohio and Cuyahoga, Ohio (the “Plaintiffs” or “Counties”) assert in their complaints two categories of claims: “claims against the

pharmaceutical manufacturers of prescription opioid drugs that engaged in a massive false marketing campaign to drastically expand the market for such drugs and their own market share, and claims against entities in the supply chain that reaped enormous financial rewards by refusing to monitor and restrict the improper distribution of those drugs."[2] Plaintiffs further allege that "[the opioid] crisis arose from the opioid manufacturers' deliberately deceptive marketing strategy to expand opioid use, together with the distributors' equally deliberate efforts to evade restrictions on opioid distribution."[3]

10. Among the "entities in the supply chain" are distributor and pharmacy defendants Cardinal Health, Inc. ("Cardinal"); AmerisourceBergen Drug Corporation ("AmerisourceBergen"); McKesson Corporation ("McKesson"); CVS Rx Services, Inc. and CVS Indiana, LLC ("CVS"); Rite Aid of Maryland, Inc., d/b/a Mid-Atlantic Customer Support Center ("Rite Aid"); Walgreens Boots Alliance, Inc. ("Walgreens"); Wal-Mart Inc. ("Wal-Mart"); HBC Service Company ("HBC"); and H. D. Smith, LLC f/k/a H. D. Smith Wholesale Drug Company ("H.D. Smith"). In my report, I refer collectively to this group of defendants as "Distributors."[4] With respect to Distributors, the Plaintiffs allege: "The failure of the Defendants to maintain effective controls, and to investigate, report, and take steps to

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2 Second Amended Complaint, *In Re National Prescription Opiate Litigation, The County of Cuyahoga, Ohio et al. v. Purdue Pharma L.P. et al.*, No.17-OP-45004 (May 18, 2018) ("Summit Complaint"), at ¶ 1; Corrected Second Amended Complaint and Jury Demand, *In Re National Prescription Opiate Litigation, The County of Summit, Ohio et al. v. Purdue Pharma L.P. et al.*, No. 18-op-45090 (May 18, 2018) ("Cuyahoga Complaint"), at ¶ 1.

3 Cuyahoga Complaint at ¶ 3; *see, also,* Summit Complaint at ¶ 3.

4 The members of this group of Distributors could change. The Summit Complaint and Cuyahoga Complaint ("Complaints") list other distributors of prescription drugs in defining the Distributor Defendants. (Cuyahoga Complaint at ¶¶ 82-95; Summit Complaint at ¶¶ 107-128.)

halt orders that they knew or should have known were suspicious breached both their statutory and common law duties."[5]

11. I have been asked by Counsel for Distributors to provide my opinion on the factors that contributed to the increased misuse and abuse of opioids over the past roughly 20 years, and explain how the experiences of Summit and Cuyahoga Counties fit with these trends. For this analysis, I summarize some of the relevant economic literature and offer my own analyses explaining the macroeconomic trends and discuss how these trends fit with the "deaths of despair" literature. I do this nationally as well as for Ohio and for Summit and Cuyahoga Counties.

12. I have also been asked by Counsel for Distributors to respond to the analyses proffered by Professor David Cutler, which he uses to provide an estimate of the share of the alleged harms allegedly incurred by the Cuyahoga and Summit Counties that are attributable to the alleged misconduct of manufacturers and distributors. As part of my analysis, I have reviewed reports on behalf of Plaintiffs by Professors David Cutler, Jonathan Gruber, Thomas McGuire, and Meredith Rosenthal.[6] I have also reviewed the two reports on behalf of Plaintiffs by Dr. Craig J. McCann.[7] I respond to some of the opinions expressed in these reports as well below.

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5 Summit Complaint at ¶ 498; Cuyahoga Complaint at ¶ 466.

6 Expert Report of Professor David Cutler, March 25, 2019 ("Cutler Report"); Expert Report of Professor Jonathan Gruber, March 25, 2019 ("Gruber Report"); Expert Report of Thomas McGuire: Damages to Bellwethers, March 25, 2019 ("McGuire Damages Report"); and Expert Report of Professor Meredith Rosenthal, March 25, 2019 ("Rosenthal Report").

7 Expert Report of Craig J. McCann, Ph.D., CFA, March 25, 2019 ("McCann Report"); and Second Supplemental Expert Report of Craig J. McCann, Ph.D., CFA, April 15, 2019 ("McCann Supplemental Report").

B. Professor Cutler's Approach

13. Professor Cutler provides "an evaluation of the impact of prescription opioid shipments on harms that impose costs" on Summit and Cuyahoga Counties.[8] As part of this evaluation, he "presents estimates of the share of various opioid-related harms faced by" Summit and Cuyahoga Counties that are "attributable to defendants' misconduct."[9] To arrive at this estimate of the share of alleged harms faced by the two Counties, Professor Cutler multiplies the following three component calculations:[10]

- The share of alleged harms attributable to opioids;
- The share of any alleged opioid harms attributable to opioid shipments; and
- The share of opioid shipments due to Defendants' alleged misconduct.

14. Professor Cutler estimates the first two components using analyses presented in his report. For the third component, Professor Cutler relies on Professor Rosenthal's estimates of the impact of Defendants' alleged marketing misconduct on prescription opioids.[11] Professor Cutler also presents in the Appendix III.I to his report, estimates of the share of alleged harms attributable to all shipments (which does not require the third component); and in Appendix III.J to his report, "an example of how [his] analysis can be applied if appropriate data become available to estimate the share of prescription opioid

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8 Cutler Report at ¶ 8.

9 Cutler Report at ¶ 15.

10 Cutler Report at ¶ 23.

11 Professor Rosenthal estimates the effect of the alleged marketing misconduct on opioid prescriptions, and Professor Cutler applies this estimate to prescription opioid shipments.

shipments that reflect distributor misconduct" (which uses a different set of numbers for the third component).[12]

15. Professor McGuire then uses Professor Cutler's estimates to determine the damages allegedly owed to Plaintiffs. Professor McGuire arrives at his damages figures by estimating the affected costs in the various divisions of Summit and Cuyahoga Counties and multiplying those figures by Professor Cutler's estimates of the share of alleged harm attributable to Defendants' alleged misconduct.[13]

16. Professor Cutler relies on the opinions of Professor Gruber for background on the opioid crisis and to inform his views on the relationship between shipments of prescription opioids and alleged opioid-related harms.[14]

C. Summary of Conclusions

17. Based on my review of Professor Cutler's methodology and economic analyses (including Professor Cutler's use of and reliance on the opinions of Professors Gruber and Rosenthal, and the use of Professor Cutler's analyses by Professor McGuire), I have concluded that Professor Cutler's methodology and economic analyses are seriously flawed. His analysis does not yield an appropriate or reliable estimate of the effect of prescription

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[12] Cutler Report Appendix III.J at ¶ 5 . Professor Cutler testified, "These percentages were given to me by counsel who said that they were the output of Mr. McCann's analysis." (Deposition of David Cutler, April 26-27, 2019 ("Cutler Deposition") at 594:16-18.) I cannot, however, find these numbers in either the McCann Report or the McCann Supplemental Report. For that reason I specifically reserve the right to change or amend the opinions in this report if, for example, the percentages in Appendix III.J of Professor Cutler's report are changed, their source is identified, or I receive information about their calculation.

[13] *See* McGuire Report at ¶ 11: "Specifically, damages are estimated by applying the estimates of the percent of harms attributable to defendants' misconduct presented in the Cutler Report (including both Approach 1 and Approach 2) to the identified affected costs in each division yielding an estimate of the damages, presented in Section V of this report."

[14] Cutler Report at ¶¶ 16-17, 30, 53.

opioid shipments on any costs incurred by Plaintiffs, and his use of his estimates in conjunction with Professor Rosenthal's estimate of the share of prescriptions attributable to the alleged misconduct does not yield an appropriate or reliable estimate of the share of any harms attributable to the alleged misconduct. Professor McGuire's use of Professor Cutler's estimates therefore does not yield an appropriate or reliable estimate of the dollar value of any alleged economic harms incurred by Plaintiffs.

18. The core opinions that I have reached and that I explain in detail in this report are the following:

a) Opioid abuse and other health and economic outcomes should be interpreted in the context of a long-run, multi-faceted process of decline that has affected certain areas of the United States with particular intensity.

b) The social and economic trends that have contributed to the increased misuse and abuse of opioids have had a substantial impact on Ohio as a state and on the counties of Cuyahoga and Summit specifically.

c) Professors Cutler and Gruber have not established a causal relationship between excess shipments (i.e., those shipments attributable Defendants' alleged misconduct) and opioid-related mortality.[15]

d) Professor Gruber's analyses of the relationship between shipments and mortality mask the wide variation in mortality across counties with similar levels of shipments.

e) Professor Cutler employs a cross-section regression analysis of around 400 counties to help determine the share of alleged harms attributable to the alleged misconduct. When

[15] *See* Cutler Report at ¶ 26: "This regression is used to estimate the elevation in opioid-related mortality due to shipments of prescription opioids. This is referred to as the 'direct approach' because it specifically seeks to directly model the causal effect of shipments on mortality." *See, also,* Gruber Report at ¶ 16: "There is a direct, causal relationship between the defendants' shipments of prescription opioids and the misuse and mortality from prescription opioids, with geographic areas that received higher volumes of per capita shipments of prescription opioids experiencing significantly higher rates of opioid related misuse and mortality, including the Bellwether jurisdictions." *See, also,* Gruber Report at ¶ 16: "There is a direct, causal relationship between defendants' shipments of prescription opioids and the misuse of and mortality from illicit opioids, including heroin and fentanyl, which accelerated rapidly after 2010."

properly specified, a cross-section analysis of counties measures the average impact across all of the counties included in the model. This average impact, however, does not necessarily reflect the experience of any individual county or subset of counties included in the model.

f) The coefficient from Professor Cutler's direct model cannot be used to reliably measure the relationship between excess shipments and alleged harm. Specifically, the coefficient cannot be used in conjunction with an estimate of the relationship between the alleged misconduct and shipments from either Professor Rosenthal or Dr. McCann to properly measure the effect of the alleged misconduct on any harms.

g) Professor Cutler claims to use shipments of prescription opioids as a proxy for the consumption of opioids and therefore claims to measure the relationship between opioid mortality and opioid "consumption."[16] However, differences in opioid consumption across counties reflect a variety of factors, including differences in the demand for opioids driven by factors unrelated to the alleged misconduct and not controlled for in Professor Cutler's model. Professor Cutler does not explain if or how he concludes that he has controlled for all of the factors that affect opioid demand, and he does not explain why the relationship between opioid demand and opioid mortality is informative for understanding how the alleged misconduct led to opioid-related harms.

h) When estimating the relationship between prescription opioid shipments and the alleged harms, Professor Cutler uses mortality as a proxy for harm, but he has not shown that opioid-related mortality is a reasonable proxy for the categories of harms that he ultimately attributes to shipments.

i) Professor Cutler's "indirect" models, which he uses to estimate a portion of the share of alleged harms attributable to shipments in Approach 1 and the entirety of the share of alleged harms attributable to shipments in Approach 2, do not measure a relationship between shipments and any harm. The indirect models therefore cannot be used as

[16] Cutler Report at ¶ 74: "However, data on consumption in an area are not available, so data on shipments to the area are used as a proxy for consumption."

evidence that shipments lead to harm, and they do not provide a reliable estimate of the share of any harms attributable to shipments.

j) Professor Cutler's indirect model of illicit mortality attributes any increase in illicit mortality not explained by his economic and demographic controls to the Defendants' conduct.[17] This includes, for example, increased illicit opioid use and mortality driven by changes in the price of heroin and the availability of fentanyl and carfentanil.[18] Professor Cutler presents no reliable evidence that these changes in the marketplace resulted from Defendants' alleged misconduct and thus cannot establish a causal chain. Even if Professor Cutler otherwise were able to show that the Defendants are "partially responsible" for the increase in illicit opioid mortality, it is not correct to assume that Defendants are responsible for *all* of the increase.[19]

k) Professor Cutler fails to demonstrate that shipments of prescription opioids led to "thicker" markets for opioids, contributing to an increase in illicit opioid-related mortality post-2010, thereby breaking a link in his causal chain. Evidence from data on drug seizures are not consistent with the claim that consumption of illicit opioids post-2010 is strongly correlated with pre-2010 shipments of prescription opioids, let alone causally related. Further, Professor Cutler ignores evidence that the trend of declining heroin prices started in the early- to mid-1990s, and that many cities had already seen significant price declines by 2004.

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[17] According to Professor Cutler, the economic and demographic factors imply that illicit mortality would have *decreased* in the but-for world. So, he is actually attributing *more* than 100 percent of the increase in illicit mortality to shipments. *See* Cutler Report at Figure III.5.

[18] Ciccarone, Daniel, "Fentanyl in the US heroin supply: A rapidly changing risk environment," *International Journal of Drug Policy 46*, 2017, pp. 107-111, ("Ciccarone (2017)") at pp. 107-108; *See* O'Donnell, Julie, R. Matthew Gladden, Christine L. Mattson, and Mbabazi Kariisa, "Notes from the Field: Overdose Deaths with Carfentanil and Other Fentanyl Analogs Detected — 10 States, July 2016–June 2017," *CDC Morbidity and Mortality Weekly Report 67(27)*, July 2018, pp. 767–768; *See, also*, "Fentanyl Drives Rise in Opioid-Linked Deaths in U.S.", Drugs.com, available at https://www.drugs.com/news/fentanyl-drives-rise-opioid-linked-deaths-u-s-66864.html.

[19] Cutler Report at ¶ 71: "[S]ome of the factors that contributed to the increase in mortality from illicit opioids after 2010 cannot be incorporated into a statistical analysis like that which is indicated for the analysis through 2010. However, the presence and sophistication of drug networks is partially a result of opioid shipments prior to 2010, as they created 'thicker markets' for illegal products."

l) Professor Cutler's Approach 1 is internally inconsistent with regards to the conclusions that it draws about the effect of prescription opioid shipments on mortality. In Approach 1, Professor Cutler uses his direct model to show a positive relationship between shipments and mortality, which he interprets as evidence that more shipments lead to more harm.[20] Also in Approach 1, Professor Cutler motivates his use of an indirect model by claiming that a *decline* in shipments leads to more mortality.[21] This inconsistency in Professor Cutler's theory – that more shipments lead to more harm and reducing shipments also leads to more harm – shows that his methodology is unreliable.

m) Professor Cutler's stated reasoning for using his direct model through to year 2010 ("to estimate the relationship between the increase in opioid-related mortality in a geographic area and per capita shipments of prescription opioids to that geographic area"[22]) and an indirect model to explain mortality after 2010 (because "after 2010 declines in shipments of prescription opioids generated increased demand for illicit opioids"[23]) implicitly acknowledges that there is no consistent directional relationship between prescription opioids shipments and mortality. A direct implication of his analysis is that neither of his models would be reliable since both forces (if they were present) would presumably operate in both time periods.

n) Professor Cutler motivates his use of a different model and econometric approach for the 2011 to 2016 period than he used for the 2006 to 2010 period by claiming that, around 2010, prescription opioid abusers switched to illicit opioids.[24] However, when he estimates the share of post-2010 licit and illicit opioid harms attributable to shipments, he

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20 Cutler Report at ¶ 92: "The [direct model regression] results indicate that, all else equal, each unit increase in shipments between 1997 and 2010 (measured in MME per capita per day) raises the mortality rate by 4.39 deaths per 100,000, an increase of more than 160 percent over the average rate in the base period. A unit increase in shipments corresponds to a 69 percent increase from the average shipment level across all areas."

21 Cutler Report at ¶ 69: "As shown above, after 2010 declines in shipments of prescription opioids generated increased demand for illicit opioids and rapid increase in deaths due to illicit opioids."

22 Cutler Report at ¶ 65.

23 Cutler Report at ¶ 69.

24 *See* Cutler Deposition at 546:20-24: "Q. And this is happening at a period [2011-2016] where, according to your theory, folks who are addicted to prescription opioids were substituting into illegal opioids, right? A. Yes, that is correct."

does not take into account this substitution.[25] Rather, an outcome of his methodology is that the estimated levels of *licit* mortality attributable to shipments increased from 2011 through 2016. Professor Cutler testified that he did not have any evidence to support his claim that the licit mortality attributable to shipments increased during a period when shipments were declining and, according to his own theory, opioid abusers were substituting from licit to illicit opioids.[26]

o) Professor Cutler runs a regression that purports to show that counties with higher prescription opioid shipments on average had smaller reductions in property and violent crime. Professor Cutler incorrectly interprets the results of these analyses as showing that prescription opioid shipments lead to more crime, and he does not seem to consider the alternative explanation that counties with more criminal activity have higher demand for opioids, and higher demand for drug abuse generally. This alternative explanation is consistent with the literature that the misuse and abuse of opioids and other drugs must be viewed in the context of the long-term economic and social decline that contributed to a variety of negative outcomes in affected areas.

p) Professor Cutler purports to estimate the share of various categories of alleged harms that are attributable to opioids. These alleged harms include increased criminal activity, increased demand for addiction and mental health services, increased demand for child and family services, and increased demand for the services of medical examiners. In calculating the share of alleged harms attributable to the alleged misconduct, Professor Cutler uses opioid-related mortality as a proxy for the various categories of harms, but does not offer an analysis to demonstrate why mortality is good proxy.

q) Professor Cutler's estimates of the share of criminal activity attributable to shipments do not consider that some people who were arrested for selling illicit opioids, or for

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25 Throughout my report, I use the terms "licit opioids" to refer to prescription opioids, and "licit mortality" to refer to deaths attributable to the misuse and abuse of prescription opioids. Licit opioids would therefore include prescription opioids obtained through illicit channels, and licit mortality would include deaths attributable to prescription opioids obtained through illicit channels.

26 *See* Cutler Deposition at 547:1-548:13.

committing crimes to obtain opioids, would sell or use different drugs or otherwise engage in different types of criminal activity in the absence of opioids.

19. The rest of my report is organized as follows: In Section III, I explain the long-run economic decline and other social and demographic changes that have affected certain regions of the United States with particular intensity and that have contributed to the increase in opioid misuse and abuse. In Section IV, I discuss how drug abuse and mortality are part of a wider phenomenon described in the literature as "deaths of despair" and how these deaths of despair are viewed as outcomes of a long-run process of economic, social, and institutional decline. In Section V, I provide background on the state of Ohio and on Summit and Cuyahoga Counties and explain how the trends discussed in Sections III and IV have had a substantial impact in the state and Counties. In Section VI, I explain why Professors Cutler and Gruber have not established a causal relationship between shipments of prescription opioids and any opioid-related harms. In Section VII, I explain the flaws in Professor Cutler's estimate of the share of any opioid-related harms attributable to shipments. In Section VIII, I discuss flaws in Professor Cutler's estimate of the share of alleged harms attributable to opioids.

III. OPIOID ABUSE AND OTHER HEALTH AND ECONOMIC OUTCOMES SHOULD BE INTERPRETED IN THE CONTEXT OF A MULTIFACETED, DECADES-LONG PROCESS THAT HAS AFFECTED CERTAIN REGIONS OF THE UNITED STATES WITH PARTICULAR INTENSITY

20. Plaintiffs' experts argue that excessive opioid shipments led to opioid abuse, which in turn led to a variety of negative health and economic outcomes in the affected areas.[27] In this section of my report, I rely on publicly available data and a variety of academic

[27] Cutler Report at Section III.C; Gruber Report at Section IV, at ¶ 72; McGuire Damages Report at ¶ 14.

studies to show why the opioid-abuse crisis and other health and economic outcomes should be interpreted in the context of a long-run, multi-faceted process of decline that has affected certain areas of the United States with particular intensity, including Summit and Cuyahoga Counties.

21. Two strands of literature emphasize the substantial role that long-term changes have played in generating negative health and economic outcomes for certain demographic groups in certain regions of the country. One strand focuses on the decline of manufacturing industries in certain areas of the United States and its consequences. The other strand is the "deaths of despair" literature, which interprets the increasing distress in mid-life observed among individuals with a high-school education or less as a process of "cumulative disadvantage" with both economic and social dimensions.[28] These strands share a number of themes: for example, both highlight the steady deterioration in job opportunities for people with low levels of education, and both identify automation and globalization as key forces driving the worsening in labor-market conditions for these groups. In this section, I focus on the "manufacturing decline" strand, and in the next section I discuss the key tenets of the "death of despair" literature.

22. My view of these two literature strands is that they are complementary. The former focuses on economic issues, paying special attention to the decline of manufacturing

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[28] A recent article in *Science* suggests that the opioid crisis "may be part of a larger, longer-term process." Among other things, the article highlights the fact that "the epidemic of drug overdoses in the United States has been inexorably tracking along an exponential curve since at least 1979, well before the surge in opioid prescribing in the mid-1990s." *See* H. Jalal, J. Buchanich, M. Roberts, L. Balmert, K. Zhang, and D. Burke, "Changing dynamics of the drug overdose epidemic in the United States from 1979 through 2016," Science 361 (21 September 2018), 1-6, at p. 5. Just as the Case-Deaton articles emphasize a long-term process of "cumulative disadvantage," the Jalal et al (2018) article highlights the existence of "multiple subepidemics" that are held together "into a smooth exponential trajectory" (p. 5). The article points out that the historical pattern "of predictable growth for at least 38 years suggests that the current opioid epidemic may be a more recent manifestation of an ongoing longer-term process." See Jalal et al (2018), at p.1.

industries in the United States and its consequences. The latter provides a more comprehensive approach to the distress experienced by certain demographic groups. In this second strand, economic problems are studied as part of a larger picture that includes social problems, the decline of institutions such as churches and unions, the deterioration of the family and of parental relations, and also the despair that arises from unfulfilled expectations. Although in my view economic problems – and especially labor-market issues – are central to many of the trends discussed here, the opioid crisis cannot be explained without taking these other dimensions into account.

23. In their reports, Professor Cutler and Professor Gruber do not take these other dimensions adequately into account. Although they acknowledge and control for some economic and demographic factors, their opinions do not reliably account for the broad-based, long-run trends summarized below. The evidence presented here suggests that one of the driving forces behind opioid abuse (and many other health and economic outcomes) was a process of long-term economic, social, and institutional decline that affected certain regions of the country with particular intensity, including Summit and Cuyahoga Counties.

A. The Decline of Manufacturing Employment in the United States Started in the Late 1970s and Accelerated in the 2000s

24. Here, I summarize the findings of the academic literature on the decline in manufacturing employment. This literature ties the opioid crisis (as well as several other economic and health outcomes) to this long-term decline in manufacturing employment and its consequences.

1. Manufacturing became an increasingly important part of the US economy from 1946 through 1978

25. In order to understand the opioid-abuse crisis of recent years, it is necessary to understand the long-run evolution of the American economy after World War II. In this section of my report, I present this historical perspective.

26. After the end of World War II, the American economy experienced a dramatic transformation.[29] Between 1946 and 1975, living standards doubled and America became a "middle-class nation."[30]

27. In those decades, the rise in middle-class incomes was driven by growing productivity in manufacturing industries such as cars, chemicals, and steel. Manufacturing centers such as Detroit, Cleveland, Akron, Gary, and Pittsburgh thrived. Worker productivity in manufacturing rose at a fast pace, which evidence suggests was due to better management practices and heavy capital investment.[31] A factory worker in 1975 was able to produce twice as much as in 1946.[32] While productivity growth happened mainly in manufacturing industries, wages grew rapidly not only in manufacturing but also in other areas of the economy, and durable goods became affordable for middle-class families.[33]

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29 I draw from Moretti, Enrico, *The New Geography of Jobs*, Mariner Books, 2013, ("Moretti (2013)") at pp. 19-20.

30 Moretti (2013) at p. 20.

31 Moretti (2013) at pp. 20-21.

32 Moretti (2013) at p. 21.

33 Moretti (2013) at pp. 20-21.

2. The decline in manufacturing employment accelerated after the year 2000

28. Manufacturing employment in the United States peaked in the late 1970s. In the 1980s, manufacturing employment stopped growing and then it started declining.[34]

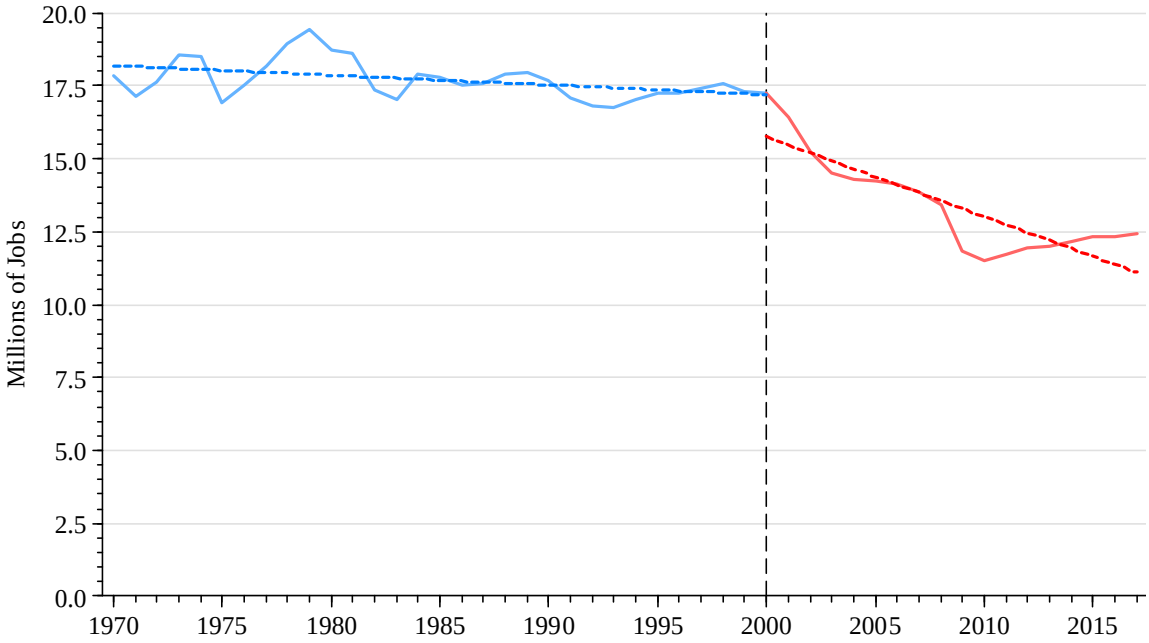
29. According to a recent academic study co-authored by economists Charles, Hurst, and Schwartz, the U.S. economy lost about two million manufacturing jobs between 1980 and 2000. After 2000, the fall in manufacturing jobs accelerated to the point that six million jobs were eliminated between 2000 and 2010, with most of the losses happening before the Great Recession of 2008. After the Great Recession, manufacturing employment remained at low levels, rebounding somewhat from the trough. Between 2000 and 2017, about 5.5 million manufacturing jobs disappeared in the United States, according to the Charles et al. study.[35] Exhibit 1 shows similar trends in the evolution of manufacturing employment in the United States.

[34] Moretti (2013) at pp. 21-22.

[35] Charles, Kerwin Kofi, Erik Hurst, and Mariel Schwartz, "The Transformation of Manufacturing and the Decline in U.S. Employment," *HCEO Working Paper Series*, May 2018, pp.1-72, ("Charles et al. (2018)") at p. 12.

Exhibit 1

U.S. Manufacturing Employment



Source: FRED All Employees Manufacturing data.

3. The decline in manufacturing employment was driven by technological change and trade shocks

30. The literature has explored two explanations for the decline in manufacturing employment and establishments. One of them emphasizes the adoption of production techniques that use more capital and less labor, and the other highlights the impact of international trade, particularly trade with China. In a 1992 study I co-authored with economist Lawrence Katz, we analyzed the role these factors played in driving changes in relative wages during the 1963-1987 period.[36]

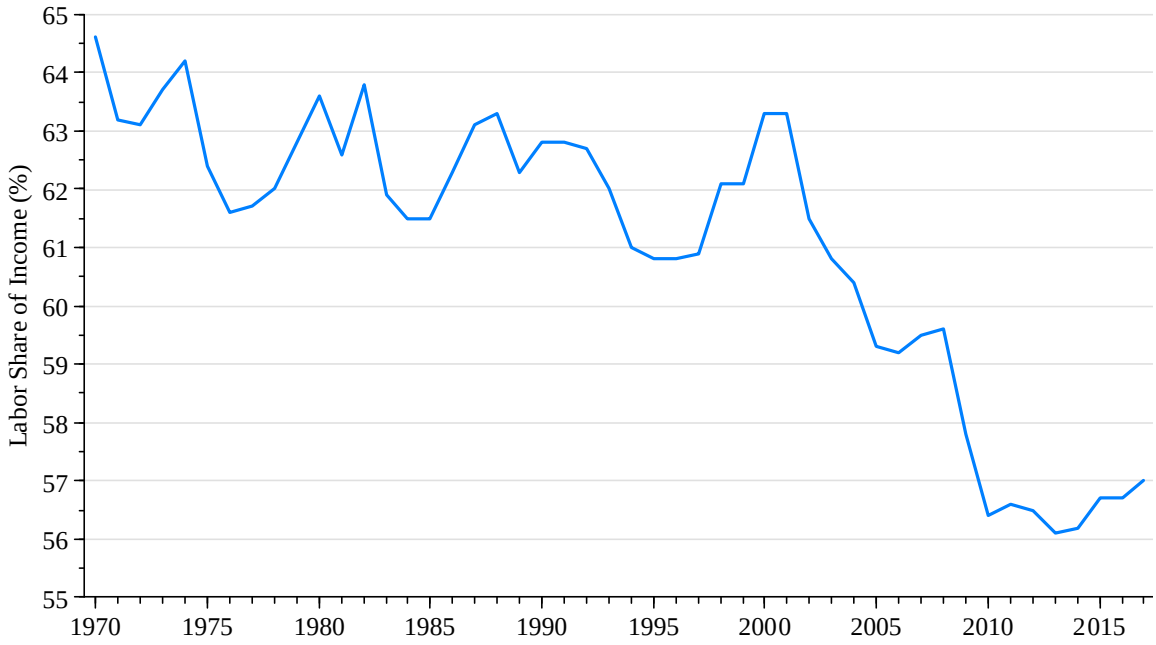
[36] Katz, Lawrence F., and Kevin M. Murphy, "Change in Relative Wages, 1963-1987: Supply and Demand Factors," *The Quarterly Journal of Economics 107:1*, February 1992, pp. 35-78 ("Katz and Murphy (1992)").

31. The first explanation focuses on the adoption of labor-saving production techniques. Efficiency gains in capital-producing sectors have induced firms to replace labor with capital to such an extent that the labor share of income has declined.[37]

32. Exhibit 2 shows that the labor share in the United States fluctuated (with a declining trend) through the late 1990s, and plunged after the year 2000. According to the Charles et al study, the labor share in the U.S. manufacturing sector declined by about 20 percent between 2000 and 2015.[38]

Exhibit 2

U.S. Labor Share of Income



Source: BLS Labor Productivity and Costs.

37 Karabarbounis, Loukas, and Brent Neiman, "The Global Decline of the Labor Share," *NBER Working Paper Series*, June 2013, pp.1-47, at p. 1. This study was published under the same title in *The Quarterly Journal of Economics 129:1*, 2014, pp. 61-103.

38 Charles et al. (2018) at p. 15.

33. The other explanation for the decline in manufacturing employment focuses on international trade, and particularly trade with China. A recent academic study examined the effect of rising Chinese import competition between 1990 and 2007 on U.S. local labor markets.[39] The study found that rising import competition "causes higher unemployment, lower labor force participation, and reduced wages in local labor markets that house import-competing manufacturing industries."[40] The authors also found that, in those labor markets that were most intensely exposed to trade, transfer benefit payments for unemployment, disability, retirement, and healthcare rose sharply.[41]

4. Manufacturing industries are using less labor than before and, in addition, are using different types of labor

34. The decline in manufacturing employment has affected more intensely those with lower levels of education. The Charles et al study cited earlier examined the time-series patterns in the share of males and females aged 21 to 55 of different education levels working in the manufacturing sector. It found that the largest decline happened among those with the lowest levels of educational attainment.[42] Exhibit 3, shows the evolution of manufacturing employment by level of educational attainment, and is consistent with these findings.

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39 Autor, David, David Dorn, and Gordon H. Hanson, "The China Syndrome: Local Labor Market Effects of Import Competition in the United States," *American Economic Review 103:6*, 2013, pp. 2121-2168 ("Autor et al. (2013)").

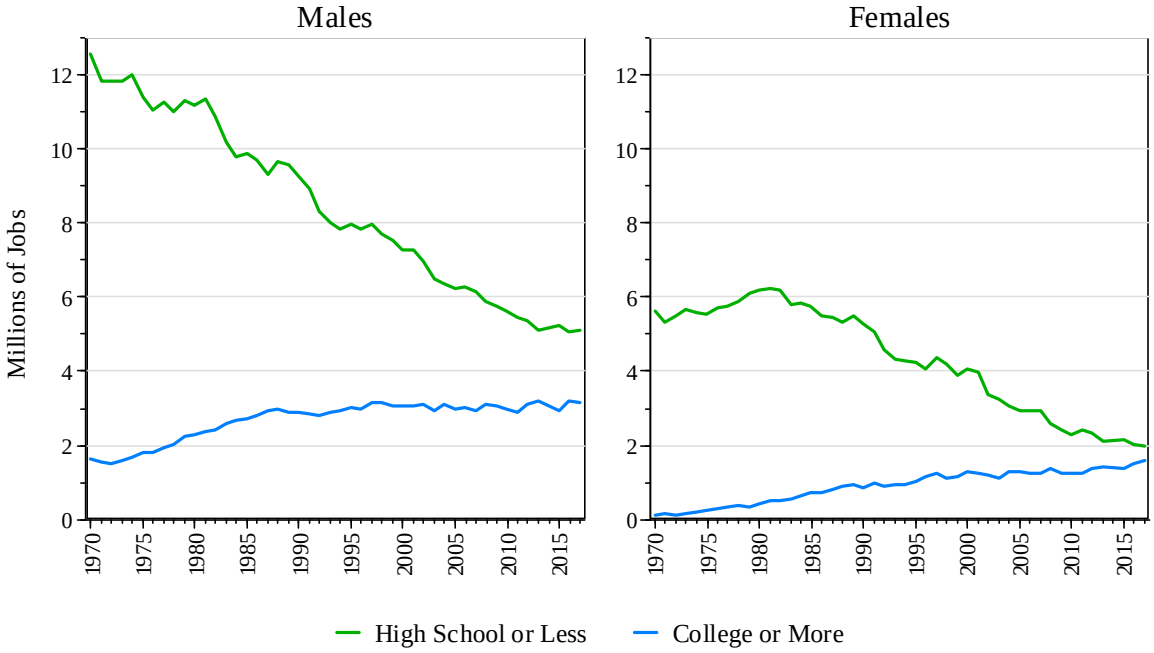
40 Autor et al. (2013) at p. 2121.

41 Autor et al. (2013) at p. 2121.

42 Charles et al. (2018) at p. 22.

Exhibit 3

U.S. Manufacturing Employment by Level of Educational Attainment



Source: IPUMS-CPS.

35. As a consequence of these differential trends across educational groups, manufacturing has become a more highly-skilled sector. The share of all manufacturing workers who are college educated has increased sharply in recent decades.[43]

5. The decline in manufacturing employment has affected different geographic regions differently

36. The decline in manufacturing employment and the changes in the skill composition of such employment discussed here have affected different regions of the United States with differential intensity. Specifically, the regions that have been affected the most

43 Charles et al. (2018) at p. 22.

are those that had relatively large shares of manufacturing employment when these transformations started in the late 1970s.

37. The economist Enrico Moretti puts it as follows:

> *Manufacturing is no longer the engine of prosperity for local communities. If anything, the opposite is true. The big manufacturing centers of America, once proud and wealthy, have been humbled and are now struggling with a shrinking population and difficult economic prospects. […]. Between the 2000 and 2010 censuses, the metropolitan area that experienced the biggest drop in population was New Orleans, because of Hurricane Katrina. But just below New Orleans came Detroit (minus 25 percent), Cleveland (minus 17 percent), Cincinnati (minus 10 percent), Pittsburgh (minus 8 percent), Toledo (minus 8 percent), and St. Louis (minus 8 percent). It is as if year after year Rust Belt cities keep being hit by their own Hurricane Katrina.*[44]

B. The Decline in Manufacturing Employment Has Brought about a Decline in Labor Force Participation and Working Hours for Prime-Age Men and Women

1. There has been a decades-long decline in work propensity among prime-age individuals, especially those with lower levels of education

38. The decline in manufacturing employment was not the only significant transformation in the American economy in recent decades. There was also a substantial collapse in the propensity to work among prime-age individuals, and especially among men with relatively low levels of education.

39. In a 1991 study I co-authored with economists Chinhui Juhn and Robert Topel, we examined the evolution of unemployment and non-participation among men since 1967.

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44 Moretti (2013) at p. 23.

We found a trend of rising joblessness "heavily concentrated on less skilled individuals." For persons in the lowest decile of the wage distribution, we estimated that "jobless time increased by more than 16 percentage points (8 weeks) between the late 1960s and the late 1980s." We also found that growing joblessness was accounted for by both rising unemployment and rising non-participation in the labor force.[45]

40. In a 2002 study I co-authored with Juhn and Topel, we showed that, although some of the labor-market trends improved for less skilled men in the 1990s, not all of them did. Specifically, we found that, although unemployment among the least skilled fell, the rising trend of non-participation in the labor market among these individuals continued during the 1990s.[46]

41. The Charles et al study cited above showed that, from 1976 through 2000, men aged 21-55 worked slightly more than 1,950 hours per year, on average, at the peak of business cycles. Annual hours began falling around the year 2000, well before the Great Recession of 2008. Hours plunged during the Great Recession and rebounded somewhat thereafter. Taking into account the recovery that happened after the Great Recession, the decline between 2000 and 2016 was from 1,950 hours to less than 1,800 hours.[47] Exhibit 4 presents the evolution of average hours worked per week for males aged 25 to 54, and reveals similar trends to those identified by Charles et al.

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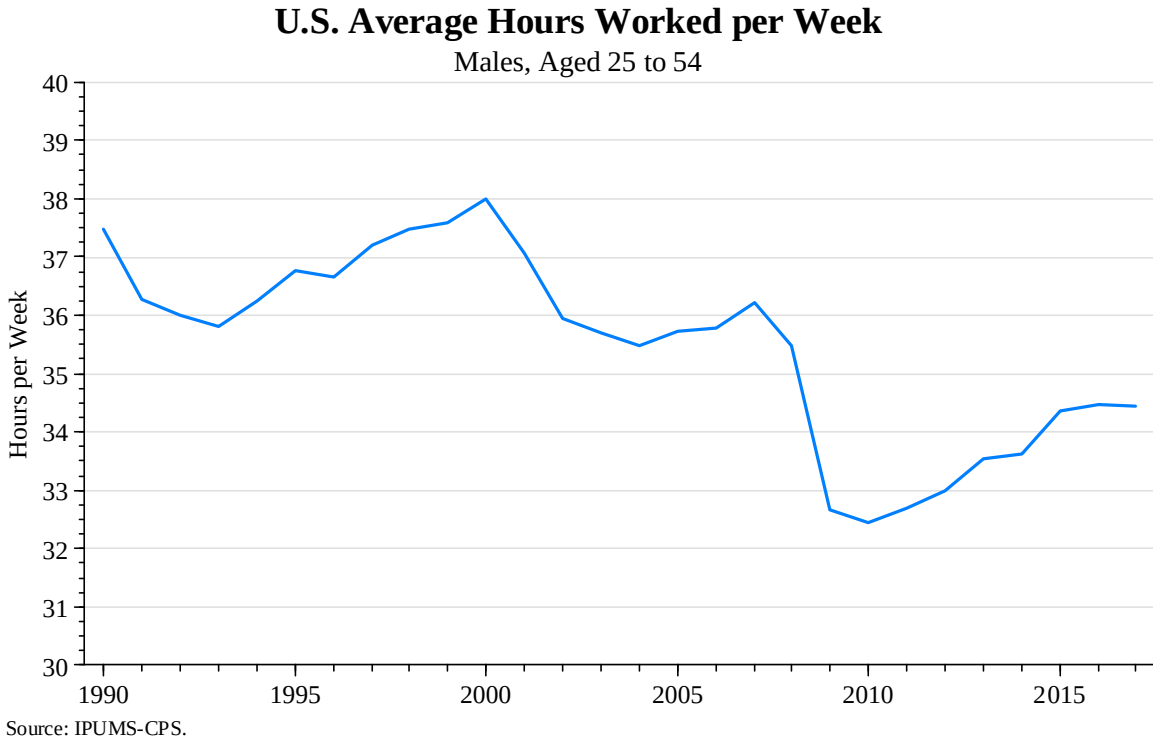
45 Juhn, Chinhui, Kevin M. Murphy, and Robert H. Topel, "Why Has the Natural Rate of Unemployment Increased Over Time?," *Brookings Papers on Economic Activity 2*, 1991, pp. 75-142 and especially p. 78.

46 Juhn, Chinhui, Kevin M. Murphy, and Robert H. Topel, "Current Unemployment, Historically Contemplated," *Brookings Papers on Economic Activity 1*, 2002, pp. 79-116.

47 Charles et al. (2018) at pp. 5-6. Annual hours worked are calculated by multiplying weeks worked during the prior calendar year by the number of hours per week the person usually work.

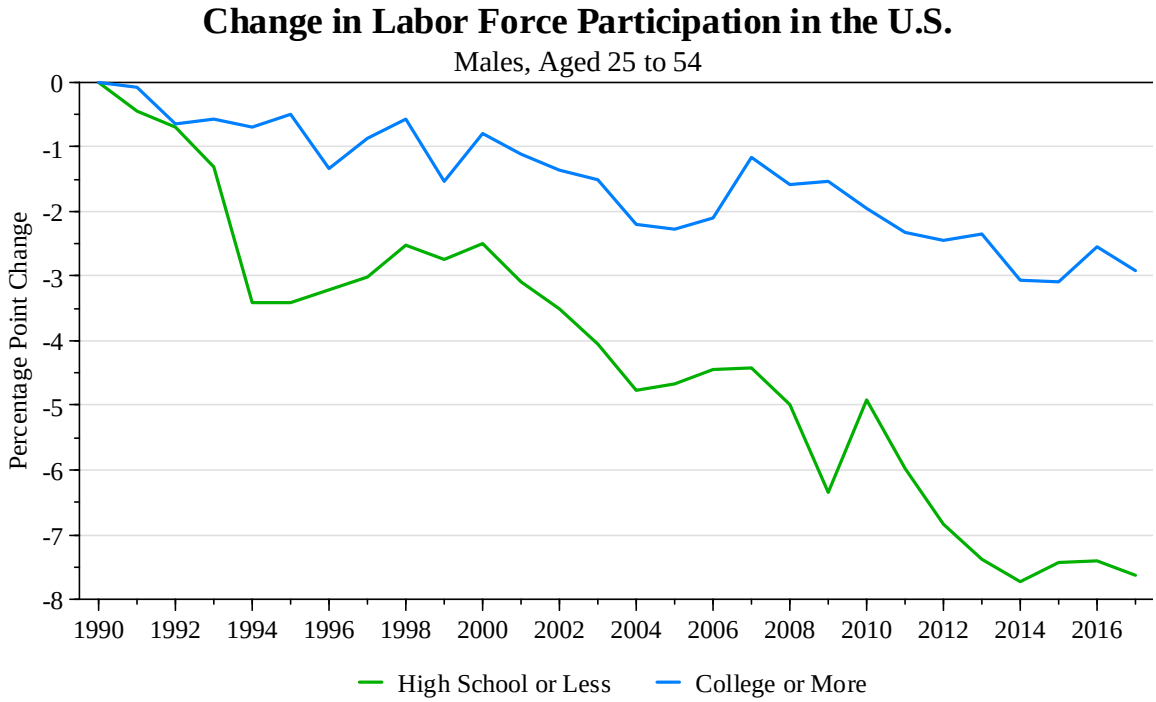
Exhibit 4



42. Charles et al showed that almost all of the decline in hours between 2000 and 2016 was caused by a fall along the extensive margin of labor supply – that is, by changes in employment participation as opposed to changes in hours worked by those who are employed.[48] The decline in participation was larger for individuals with lower levels of educational achievement. Exhibit 5 shows the evolution in labor force participation for males aged 25 to 54, and reveals also a much stronger decline in participation for individuals with a high-school education or less.

[48] Charles et al. (2018) at pp. 5-10.

Exhibit 5



Source: IPUMS-CPS.

43. Charles et al explored the connections between the decline in local manufacturing labor demand in the 2000s and changes in local annual hours and employment rates for prime-age males and females. The study started by identifying those areas of the country in which manufacturing employment was heavily concentrated at the starting point. It found that much of the manufacturing industry in the United States was concentrated in the Midwest and South East in 2000. States such as Georgia, Indiana, western Kentucky, Michigan, Minnesota, North Carolina, Ohio, Pennsylvania, South Carolina, Tennessee, West Virginia, and Wisconsin had "commuting zones" with large fractions of the population working in manufacturing industries in 2000.[49]

[49] Charles et al. (2018) at p. 29. The commuting zones is the geographic unit used in this academic study (and in others as well).

44. Regions where manufacturing industries were heavily concentrated in 2000 experienced the largest declines in manufacturing share between 2000 and 2016. In addition, and most importantly, the study found a strong relationship between the manufacturing share of a region in 2000 and the subsequent change in employment rates in the region between 2000 and 2016. Specifically, the study found that the decline in the manufacturing share of a region between 2000 and 2016 accounted for a substantial portion of the decline in employment rates for men and women in the region.[50]

2. The decline in manufacturing employment has generated a decline in real wages for the affected demographic groups, which has negatively impacted worker wellbeing

45. Charles et al also explored the connections between the decline in manufacturing employment in certain regions of the country and changes in real wages in those areas. It found that as employment and hours fell, so did wages in the affected regions. The authors wrote: "We take this as strong evidence that the reductions in employment and hours that we estimate do not primarily reflect reduced labor supply, but instead are primarily the product of decreased labor demand in commuting zones."[51] These findings are similar to those reported for a much earlier period in the 1992 Katz-Murphy study cited earlier: "we found that changes in labor demand also had a substantial effect on the structure of wages between the 1960s and the late 1980s, depressing the wages of the least skilled relative to the most skilled workers in the economy."[52]

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50 Charles et al. (2018) at p. 38.

51 Charles et al. (2018) at p. 37.

52 Katz and Murphy (1992).

3. Summary

46. The picture of American macroeconomic evolution after World War II presented above can be summarized as follows. Between the mid-1940s and the early to mid-1970s, the American economy underwent a dramatic transformation driven, to a good extent, by the rapid growth of manufacturing industries. The trends, however, reversed in the late 1970s and early 1980s: manufacturing employment stopped growing and, in the 1980s, started to decline, with the process accelerating after the year 2000.

47. The fast decline of manufacturing employment, which was driven by an increase in import competition (especially from China in more recent years) and by the introduction of labor-saving production techniques, brought about a number of consequences. First, there was a reduction in the number of hours worked by prime-age individuals, especially men. Second, this reduction was driven mainly by a fall in employment participation. Third, the process affected mainly men and women with low levels of educational achievement. Fourth, the decline in employment was accompanied by a decline in real wages, which suggests that a shift in labor demand (rather than a shift in supply) was at work. And finally, it affected different regions of the country differently, with the strongest impact occurring in those areas with heavy concentrations of manufacturing employment at the starting point.

48. Next, I review several academic studies that have uncovered connections between these long-run macroeconomic trends and a variety of health and economic outcomes.

C. The Opioid-Abuse Crisis and Other Health and Economic Outcomes Have to Be Interpreted in the Context of This Decade-Long Process of Manufacturing Decline

49. Several academic studies have interpreted the opioid-abuse crisis and other health outcomes in the context of the macroeconomic trends discussed above.

1. Manufacturing decline has had an effect on opioid use and abuse

50. The same study that uncovered the links between manufacturing decline and employment reductions also explored the connections between manufacturing decline and worker wellbeing, especially regarding opioid use and abuse.[53] The authors asked whether local adverse shocks to manufacturing led to an increase in opioid use and abuse in a given area.

51. The authors first explored whether the decline in manufacturing employment between 2000 and 2016 helps explain the *level* of opioid prescriptions in 2015, and they found that it does – both at the commuting-zone and the state levels. They write: "These findings are consistent with deteriorating labor market conditions leading to higher opioid use. It appears that in places with declining demand for manufacturing workers, doctors prescribed more opioids – presumably to meet patient demand."[54]

52. The authors also explored whether the decline in manufacturing employment between 2000 and 2016 helps explain *changes* in per capita drug overdose deaths – all drug overdose deaths and opioid drug overdose deaths – during the same period. Again, they found that it does: for every one-percentage-point decline in the manufacturing employment share of prime-age workers between 2000 and 2016, drug and opioid death rates per 1,000 individuals increased by 0.04 and 0.02, respectively. For reference purposes, the national mean drug overdose rate and opioid overdose rate were 0.25 and 0.16, respectively, in 2011-2015.[55]

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53 Charles et al. (2018) at pp. 42-51.

54 Charles et al. (2018) at p. 46.

55 Charles et al. (2018) at p. 48.

53. Finally, the authors asked which specific individuals in the community increased their drug use when jobs disappeared. To answer this question, they relied on data on drug-test results for tests administered to people working or looking for work. They found that states that experienced the largest decline in their manufacturing shares between 2000 and 2016 were much more likely to be home to a failed drug test in the 2012-2016 period.[56]

54. In light of all of these results, the authors concluded: "On the whole, our results strongly suggest that local wellbeing losses associated with job and wage reductions from local manufacturing decline led to greater opioid use and increased drug and opioid deaths at the local level."[57]

2. Trade shocks have had an impact on mortality

55. The findings summarized above should be viewed in the context of a collection of academic studies that have uncovered links between the macroeconomic trends examined earlier and various health outcomes, including drug use and abuse.

56. A recent academic study explored the connections between trade liberalization and mortality.[58] The study focused on the impact of an exogenous change in policy that took place in October 2000 – the granting of Permanent Normal Trade Relations (PNTR) to China. This change in trade policy differentially exposed U.S. counties to increased international competition, with the intensity of the impact depending on the industry structure of each county at the time the policy change was introduced.

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56 Charles et al. (2018) at p. 51.

57 Charles et al. (2018) at p. 51.

58 Pierce, Justin R., and Peter K. Schott, "Trade Liberalization and Mortality: Evidence from U.S. Counties," *NBER Working Paper Series*, November 2016, pp.1-66 ("Pierce and Schott (2016)").

57. The authors focused on three types of death as potential outcomes – suicide, accidental poisoning (including drug overdoses), and alcohol-related liver disease. They found that PNTR was associated with a statistically significant relative increase in suicide, and that this effect was particularly strong among white men. They also found that PNTR was associated with a statistically significant relative increase in mortality from accidental poisoning, although in this case the results were more sensitive to model specification. They also found mixed evidence regarding the connection between PNTR and mortality from alcohol-related liver disease.[59]

58. In order to explore whether labor market disruption was the channel through which PNTR affected mortality, they examined the relationship between the policy change and several labor market outcomes. They found that the policy change was associated with persistent relative increases in unemployment rates and persistent relative declines in manufacturing employment, overall employment, labor force participation, and per capita personal income. Counties that were more exposed to trade liberalization at the starting point tended to experience stronger (negative) effects from the policy, on average. From this evidence, the authors drew the conclusion that "PNTR's relationship with mortality rates may occur at least in part via the impact of import competition on local labor markets."[60]

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59 Pierce and Schott (2016) at pp. 2-3.

60 Pierce and Schott (2016) at p. 3.

3. Trade shocks have affected marriage, fertility, and household structure

59. Another recent academic study assessed how adverse shocks to the labor market (arising mainly from trade pressure on U.S. manufacturing industries) have affected marriage, fertility, household structure, and children's living circumstances.[61]

60. Relying on variation across industries and local labor markets in exposure to import competition (particularly from China), the study identified labor-demand shocks concentrated on manufacturing, which in turn had profound implications on marriage and family structures in the affected regions. The study presented three key findings.

61. First, shocks to manufacturing labor demand, measured at the level of commuting zones, had large negative impacts on males' relative employment and annual labor earnings. The relative declines in male earnings were largest at the bottom of the earnings distribution.[62]

62. Second, these shocks curtailed the availability and desirability of potentially marriageable young men in two ways: 1) by reducing the share of men among young adults in a commuting zone, and 2) by increasing the prevalence of idleness (the state of being neither employed nor in school) among the young men who remained in the zone. This situation, in turn, led to a differential rise in male mortality from drug and alcohol poisoning, which in turn led to a decline in the male-female ratio in those areas most exposed to trade shocks.[63]

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61 Autor, David, David Dorn, and Gordon H. Hanson, "When Work Disappears: Manufacturing Decline and the Falling Marriage-Market Value of Young Men," *NBER Working Paper Series*, February 2017, Revised January 2018, pp.1-23 ("Autor et al. (2018)").

62 Autor et al. (2018) at pp. 1-2.

63 Autor et al. (2018) at p. 2.

63. Finally, the shocks also had a profound impact on marriage and family structure: they raised the fraction of mothers that are unwed, the fraction of children in single-headed, non-cohabitating households, and the fraction of children living in poverty.[64] This evidence suggests that declines in the economic prospects will generally lead to broader declines in social and economic outcomes.

IV. OPIOID ABUSE AND MORTALITY, AS WELL AS OTHER HEALTH OUTOMES, SHOULD BE INTERPRETED WITHIN THE CONTEXT OF THE "DEATHS OF DESPAIR" LITERATURE

64. In two recent articles, the economists Anne Case and Angus Deaton have highlighted a trend of rising mortality and morbidity that is specific to an ethnic, age, and educational group in the United States: white men (and women) aged 45 to 54, with a high-school degree or less.[65] These studies have drawn attention and commentary because they have uncovered a trend that breaks the pattern of declining mortality observed in other demographic groups in the United States and abroad, and for the same demographic group in other countries.

65. In their studies, Case and Deaton point out that rising mortality among middle-aged whites with a high-school education or less is driven by an increase in mortality associated with three causes: drug overdoses, suicides, and alcohol-related liver deterioration. They also emphasize the marked differences in mortality by race and education: mortality

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64 Autor et al. (2018) at p. 2.

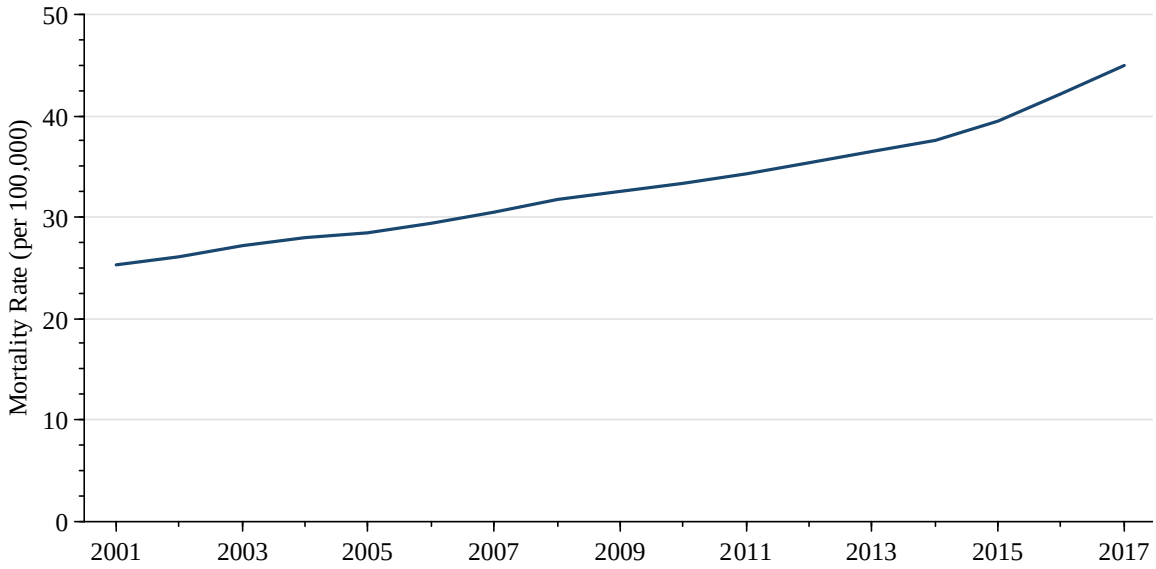
65 Case, Anne, and Angus Deaton, "Rising morbidity and mortality in midlife among white non-Hispanic Americans in the 21st century," *Proceedings of the National Academy of Sciences 112:49*, 2015, pp. 15078-15083; and Case, Anne, and Angus Deaton, "Mortality and Morbidity in the 21st Century," Brookings Papers on Economic Activity, Spring 2017, pp. 397-476 ("Case and Deaton (2017)").

among white non-Hispanics (males and women) has been rising for those without a college degree and has been declining for those with a college degree.[66]

66. Exhibit 6 shows the rising trend in mortality associated with drug overdoses, suicide, and alcohol-related liver problems in the United States. Figure 11 from the Case-Deaton 2017 study, shows that mortality from those causes has been rising for individuals with a high-school education or less but has been stable for those with a college degree or more.

Exhibit 6

U.S. Mortality Rates Related to "Deaths of Despair"

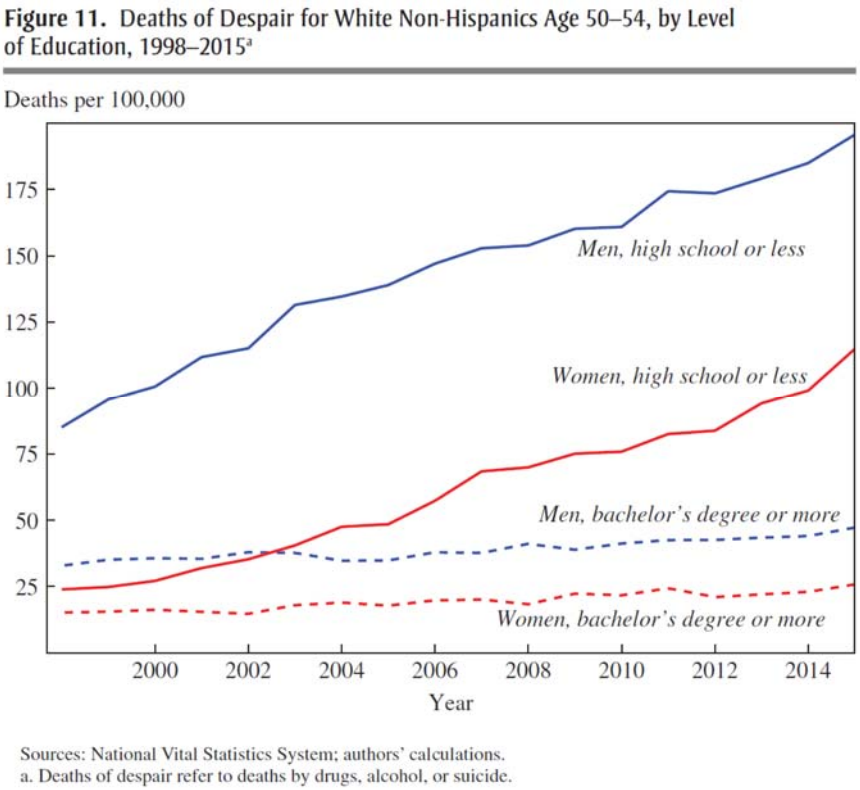


Note: Deaths of despair include suicide, poisoning by drugs or alcohol, and alcoholic liver disease and cirrhosis, based on the ICD-10 codes used by Case and Deaton (2017). The above chart is based on a three-year rolling averages of these deaths.

Source: CDC Wonder.

66 Case and Deaton (2017) at p. 397.

Figure 11 from Case and Deaton (2017)



67. In their earlier study, published in 2015, Case and Deaton documented the rising mortality and morbidity trend without offering a well-developed explanation for the patterns they observed in the data. In their more recent study, published in 2017, the authors offer an explanation in terms of "cumulative disadvantage." They emphasize the "cumulative" dimension of the problem to distinguish their explanation from one focused on "contemporaneous aggregate factors, such as income or unemployment."[67]

68. Case and Deaton argue that "some of the most convincing discussions of what has happened to working-class whites emphasize a long-term process of decline, rooted in the

67 Case and Deaton (2017) at p. 429.

steady deterioration in job opportunities for people with low education […]."[68] The process began for individuals leaving high school and entering the labor force after the early 1970s. It was a comprehensive process that had its roots in worsening labor-market conditions but was not limited to work-related trends—it encompassed the deterioration of the family and other social structures, such as unions and churches.

69. At the root of the process was technical change and globalization, which reduced the quantity and quality of opportunities available in the labor market for individuals with no more than a high-school degree.[69] One of the immediate consequences was that real wages for those with a high-school education or less declined, while the college premium increased. It has been estimated that only 60 percent of the cohort born in 1960 was better off in 1990 than their parents had been at age 30. This represented a substantial decline relative to those born in 1940, since 90 percent of them were better off at age 30 than their parents had been at the same age.[70]

70. Lower wages for middle-aged white individuals with a high-school education or less brought not only withdrawal from the labor force but also disadvantages in the marriage market: marriage rates declined, and the frequency of cohabitation increased. In turn, this led to more unstable partnerships, and to more infrequent contacts between men and their children, which was harmful both for the children and their parents.[71] Citing the work of Alan

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68 Case and Deaton (2017) at p. 429.

69 Case and Deaton (2017) at p. 430.

70 Case and Deaton (2017) at p. 430. The authors cited the key findings of a study by Chetty, Raj, et al., "The Fading American Dream: Trends in Absolute Income Mobility Since 1940," *Science Vol. 356, Issue. 6336,* 2017, pp. 398-406.

71 Case and Deaton (2017) at pp. 431-432.

Krueger, Case and Deaton also point out that half the men who are out of the labor force take pain medication, and two-thirds of those take a prescription painkiller, such as an opioid.[72]

71. Case and Deaton summarize their explanation as follows: "These slow-acting forces seem to us to be plausible candidates to explain rising morbidity and mortality, particularly suicide and the other deaths of despair, which share much with suicide. As we have emphasized elsewhere […], purely economic accounts of suicide have rarely been successful in explaining the phenomenon. If they work at all, they work through their effects on family, on spiritual fulfillment, and on how people perceive meaning and satisfaction in their lives in a way that goes beyond material success. At the same time, increasing distress, and the failure of life to turn out as expected, are consistent with people compensating through other risky behaviors such as abuse of alcohol and drug use that predispose toward the outcomes we have been discussing."[73]

72. As I pointed out above, there are a number of similarities between the "deaths of despair" and the "manufacturing decline" literature strands. Both identify declining labor-market opportunities for individuals with relatively low levels of education as central to all of these negative outcomes. Both emphasize the role that technological change and trade shocks (or globalization) have played in eliminating job opportunities for specific demographic groups in the United States. Both point out that deteriorating labor-market conditions have led to declines in real wages for these groups and also to withdrawal from the labor market.

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72 Case and Deaton (2017) at p. 433. Case and Deaton write: "Doctors also bear responsibility for their willingness to (over)prescribe drugs […], especially when they have little idea of how to cure addiction if and when it occurs." The cited study is Krueger, Alan B. et al., "Where Have All the Workers Gone? An Inquiry into the Decline of the U.S. Labor Force Participation Rate" Brookings Papers on Economic Activity, 2017, pp. 1-43.

73 Case and Deaton (2017) at pp. 433-434.

Both highlight the fact that negative labor-market outcomes have had negative implications for other areas of life, including health outcomes. The main difference between the two strands is that, whereas the "manufacturing decline" literature lays a stronger emphasis on economic conditions and their consequences, the "deaths of despair" literature also highlights the role of other factors such as social conditions, the deterioration of marriages, families, and parental relations, and the decline of institutions such as unions and churches.[74]

73. Professor Cutler was one of the academics responsible for commenting on the Case and Deaton (2017) study. He suggested that the Case-Deaton interpretation was in the tradition of sociologist Emile Durkheim: "people despair when their material and social circumstances are below what they had expected. This despair leads people to act in ways that significantly harm their health. […] At root is economic and social breakdown." And he added: "This explanation is certainly correct."[75] He also explained that Case and Deaton made a distinction between their theory of despair and a theory that focuses only on current income. In the Case-Deaton theory, "despair starts early in life, at the time of entering the labor force or before […]." Professor Cutler commented: "Again, I am tempted to believe this, though the evidence for any particular view about how expectations are formed and what income shocks imply is not as clear as one would like it to be."[76]

74. In 2018, the economist Christopher Ruhm published a study in which he challenged what he understood to be the key tenets of the "deaths of despair" theory.

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74 I discuss below in in Section VII that when Professor Cutler models opioid mortality using his "direct" model, he does not directly control for many of these contributing factors.

75 Professor Cutler's comments on Case and Deaton (2017) at p. 445.

76 Professor Cutler's comments on Case and Deaton (2017) at pp. 445-446.

Specifically, Ruhm examined "the extent to which increases in county-level drug mortality rates from 1999-2015 are due to 'deaths of despair,' measured here by deterioration in medium-run economic conditions, or if they instead are more likely to reflect changes in the 'drug environment' in ways that present differential risks to population subgroups."[77] In his study, he downplayed the role of medium-run economic conditions. He argued that the data are consistent with an explanation based on the availability and cost of drugs.[78]

75. Case and Deaton responded to Ruhm by pointing out that he had fundamentally misinterpreted their theory.[79] Specifically, in their 2017 "deaths of despair" study, Case and Deaton argued that medium-run economic conditions, and specifically changes in income for different economic groups associated with the Great Recession of 2008, were not the drivers of the increase in mortality they were focusing on.[80] Thus, there was no discrepancy between Case-Deaton and Ruhm on this point.

76. Case and Deaton distinguish their explanation from Ruhm's interpretation of their explanation by pointing out that the deaths-of-despair theory is "about *much more* than economic circumstances and goes back *much* further than 1999."[81] They write: "In our paper we talk about morbidity as well as mortality, and while we recognize the deterioration in

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77 Ruhm, Christopher J., "Deaths of Despair or Drug Problems?" NBER Working Paper 24188, January 2018, pp.1-69 ("Ruhm (2018)"), at p. 1.

78 Ruhm (2018) at p. 1.

79 Case, Anne, and Angus Deaton, "Deaths of despair redux: a response to Christopher Ruhm," January 8, 2018, available at https://www.princeton.edu/~accase/downloads/Case_and_Deaton_Comment_on_CJRuhm_Jan_2018.pdf ("Case and Deaton (2018)")

80 Case and Deaton (2018) at pp. 1-2.

81 Case and Deaton (2018) at p. 2. Emphasis is Case and Deaton's.

wages for those without a BA, we also focus on the decline in labor force participation, the decline in marriage rates, the rise of cohabitation, the rise in out of wedlock births, and of parents living apart from children that they barely know. We discuss the decline in the quality of jobs, the increasing lack of opportunity for people without a BA, as well as changing religious practices. We discuss the decline in unions, and the consequent loss of local, national, and workplace voice that workers once had. We discuss that many less-educated people have lives that are economically and socially inferior to those of their parents."[82] Put differently, Case and Deaton's "deaths of despair" theory is much more comprehensive than Ruhm's interpretation of it, and reflects a process of cumulative disadvantage that started much earlier than 1999.

77. Regarding the drug epidemic, which is the focus of Ruhm's study, Case and Deaton also write: "We do not discount the importance of the opioid epidemic, but we regard it as having added fuel to an already bad situation, and certainly not the only cause of increasing mortality."[83] Their conclusion summarizes their interpretation of the drug epidemic: "[…] we continue to believe that the broader epidemic, including opioids, is linked to the long-term decline of working-class lives, and that while economic decline is part of the story, it is only a part."[84]

V. BACKGROUND ON CUYAHOGA COUNTY AND SUMMIT COUNTY

78. The economic trends I summarized above have had a substantial impact on Ohio as a state and specifically on the counties of Cuyahoga and Summit.

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82 Case and Deaton (2018) p. 2.

83 Case and Deaton (2018) at p. 3.

84 Case and Deaton (2018) at p. 4.

A. Role of Manufacturing

1. Ohio

79. In 1990, manufacturing industries accounted for a substantial portion of total employment in the state of Ohio. Exhibit 7 shows that Ohio ranked among the top ten states in the nation by the total number of manufacturing jobs in 1990. It also ranked among the top ten by the manufacturing share of total state employment.

Exhibit 7

Ohio is Among the States with the Highest Manufacturing Employment in 1990

	Manufacturing Employment ('000s)			
State	1990	2017	Jobs Lost	Percent Change
California	2,070	1,304	-766	-37%
Ohio	**1,082**	**686**	**-396**	**-37%**
New York	968	444	-524	-54%
Texas	963	852	-111	-12%
Pennsylvania	952	562	-391	-41%
Illinois	917	575	-343	-37%
Michigan	835	615	-220	-26%
North Carolina	820	467	-353	-43%
Indiana	611	531	-80	-13%
New Jersey	529	242	-287	-54%
US State Average	356	248	-108	-30%

Source: BLS, QCEW.

2. Cuyahoga and Summit

80. Cuyahoga and Summit are located in Northeastern Ohio. They are among the most populous counties in the state. In 1990, both counties had large numbers of

manufacturing jobs: with about 158,000, Cuyahoga ranked first among all Ohio counties, and Summit ranked fifth with about 56,000.

Exhibit 8

Cuyahoga and Summit are Among the Ohio Counties with the Highest Manufacturing Employment in 1990

	Manufacturing Employment ('000s)			
County	1990	2017	Jobs Lost	Percent Change
Cuyahoga	**158**	**67**	**-91**	**-58**
Hamilton	114	50	-65	-57
Montgomery	67	28	-40	-59
Franklin	59	38	-21	-36
Summit	**56**	**29**	**-27**	**-48**
Stark	44	25	-19	-43
Lucas	39	22	-17	-43
Trumbull	33	11	-22	-67
Lorain	27	16	-11	-40
Lake	25	21	-5	-18
Average across 88 Ohio Counties	13	8	-5	-37

Source: BLS, QCEW.

81. Although both counties had large numbers of manufacturing jobs in 1990, both counties also have substantial populations and are relatively diversified. In 1990, the share of manufacturing in total county employment was about 27 percent in Summit and around 23 percent in Cuyahoga.

B. Manufacturing Decline

1. Ohio

82. I investigated which portions of the country were most affected by the long-run process of manufacturing decline examined earlier. Exhibit 9 presents a picture of the

differential intensity of the decline in manufacturing employment across states between 1990 and 2017. It shows the top ten states ranked by the magnitude of the loss in manufacturing jobs. By this measure, Ohio ranked third.

Exhibit 9

Ohio is Among the States with the Largest Declines in Manufacturing Employment from 1990 to 2017

	Manufacturing Employment ('000s)			
State	1990	2017	Jobs Lost	Percent Change
California	2,070	1,304	-766	-37
New York	968	444	-524	-54
Ohio	**1,082**	**686**	**-396**	**-37**
Pennsylvania	952	562	-391	-41
North Carolina	820	467	-353	-43
Illinois	917	575	-343	-37
New Jersey	529	242	-287	-54
Massachusetts	484	245	-239	-49
Michigan	835	615	-220	-26
Virginia	386	233	-153	-40
US State Average	356	248	-108	-30

Source: BLS, QCEW.

2. Cuyahoga and Summit

83. Cuyahoga and Summit were among the Ohio counties with the largest decline in manufacturing employment numbers. Exhibit 10 shows the number of manufacturing jobs lost between 1990 and 2017 in the Ohio counties that lost the most jobs. Cuyahoga was the county with the worst losses and Summit ranked fourth by this measure.

Exhibit 10

Cuyahoga and Summit are Among the Ohio Counties with the Largest Declines in Manufacturing Employment from 1990 to 2017

	Manufacturing Employment ('000s)			
County	1990	2017	Jobs Lost	Percent Change
Cuyahoga	**158**	**67**	**-91**	**-58**
Hamilton	114	50	-65	-57
Montgomery	67	28	-40	-59
Summit	**56**	**29**	**-27**	**-48**
Trumbull	33	11	-22	-67
Franklin	59	38	-21	-36
Stark	44	25	-19	-43
Lucas	39	22	-17	-43
Lorain	27	16	-11	-40
Clark	14	7	-7	-51
Average across 88 Ohio Counties	13	8	-5	-37

Source: BLS, QCEW.

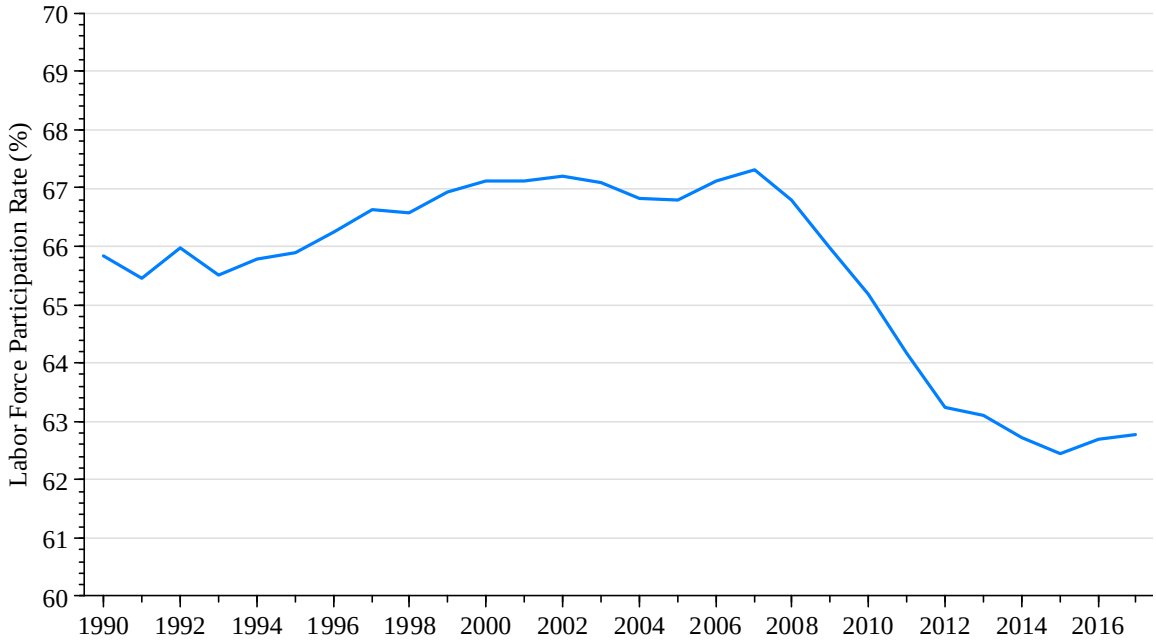
C. Employment Decline

1. Ohio

84. Declines in manufacturing employment were associated with reductions in labor force participation. Exhibit 11 shows the evolution of the labor-force-to-population ratio in Ohio. The ratio rose somewhat until the mid-2000s and then collapsed.

Exhibit 11

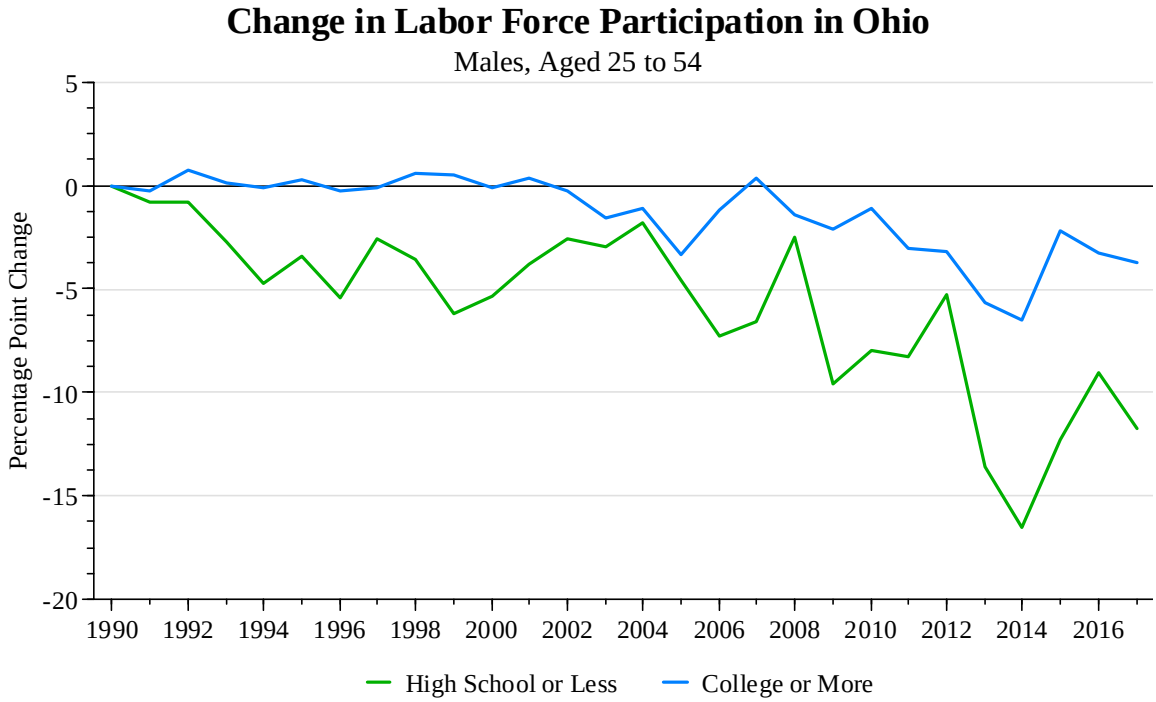
Ohio Labor Force Participation Rate



Source: BLS, LAU.

85. As it happened in the country as a whole, the decline in labor force participation in Ohio affected most intensely those individuals that had the lowest levels of education. Exhibit 12 shows that, between 1990 and 2017, labor force participation in the state declined more substantially for individuals with at most a high-school education. Further, the exhibit also shows that, even though the overall labor-force-to-population ratio only started declining in the state in the 2000s, the decline started much earlier for individuals with a high-school education or less.

Exhibit 12

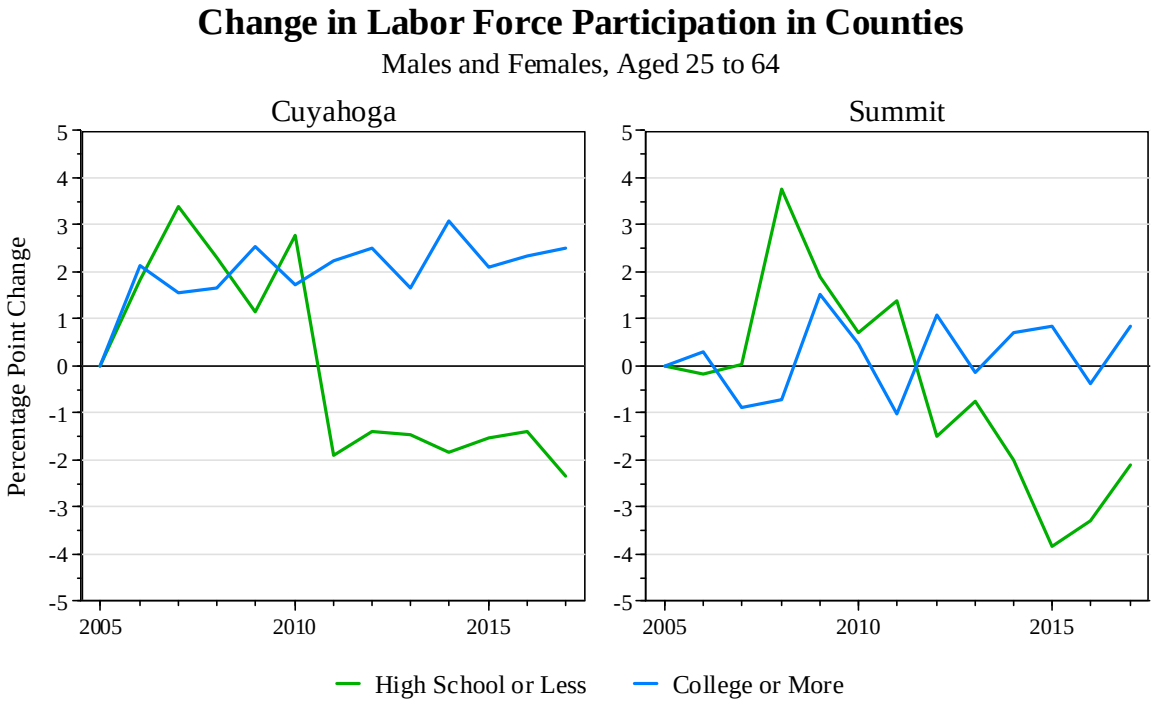


Source: IPUMS-CPS.

2. Cuyahoga and Summit

86. As in other parts of the state (and the country more generally), in Cuyahoga and Summit the decline was considerably more substantial for individuals with lower levels of education. (*See* Exhibit 13.)

Exhibit 13



Source: Census, American Community Survey, 2005-2017.

D. Opioids Shipment and Opioid-Related Deaths

1. Ohio

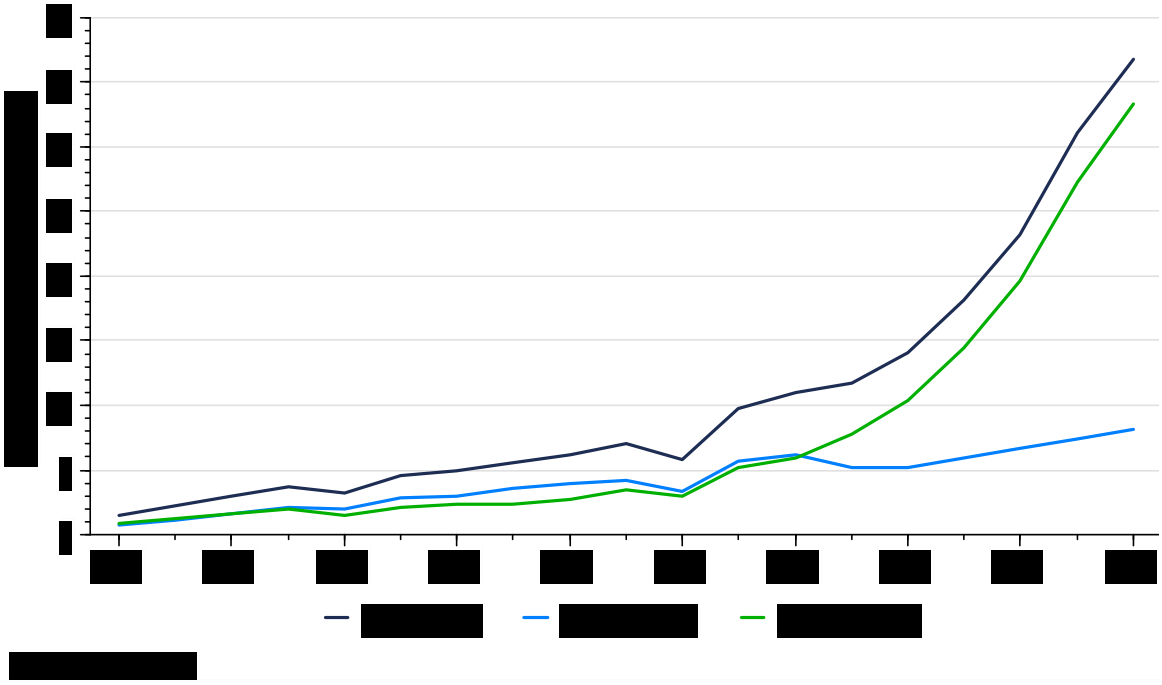
87. Exhibit 14 shows the evolution of opioid shipments to the state of Ohio between the late 1990s and 2016. Throughout that period, trends in shipments to Ohio were roughly in line with trends for the United States as a whole, [redacted]

Exhibit 14

88. Exhibit15 shows the evolution of opioid-related mortality in the state of Ohio between the late 1990s and 2017. The exhibit breaks down the evolution of total opioid-related mortality into licit-opioid mortality and illicit-opioid mortality. The exhibit shows that, although shipments did not increase after 2010, total opioid-related mortality rose at a fast pace, and illicit-opioid mortality rose much faster than licit-opioid mortality.

Exhibit 15

[redacted] Rates



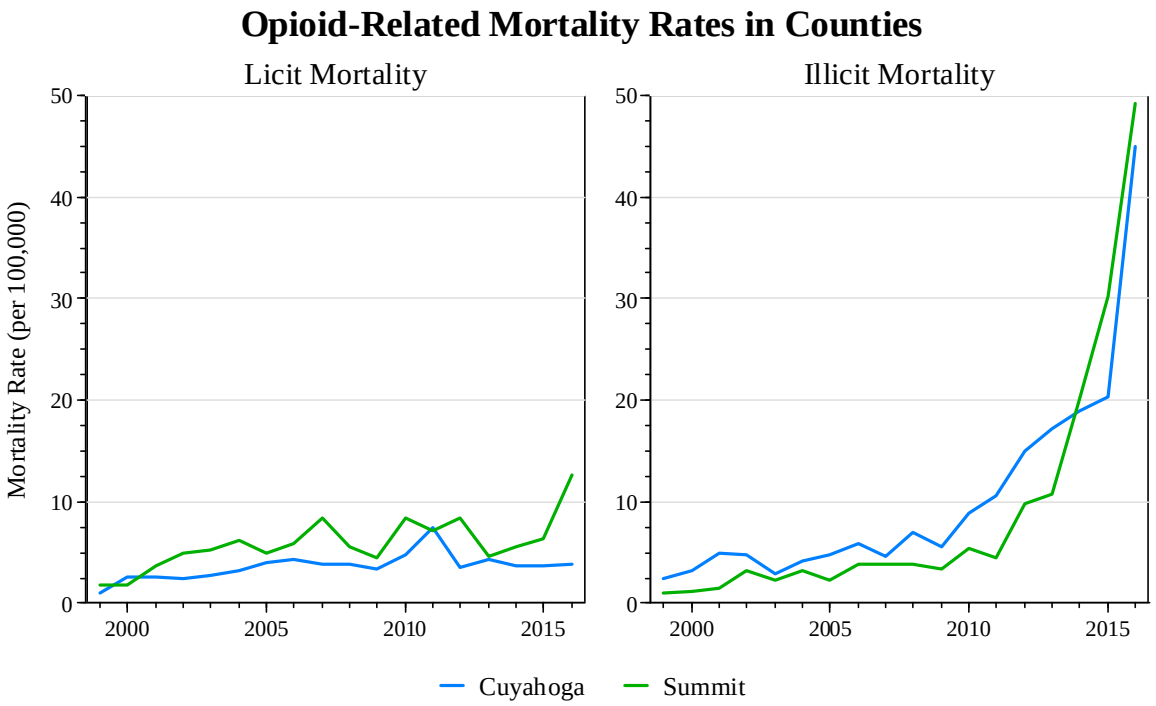
2. Cuyahoga and Summit

89. Exhibit 16 also shows the evolution of opioid shipments into the counties of Cuyahoga and Summit between the late 1990s and 2014. [redacted]

Exhibit 16

90. Exhibit 17 shows the evolution of opioid-related mortality in Cuyahoga and Summit County. The exhibit shows that licit mortality rose slowly but illicit mortality rose rapidly after 2010.

Exhibit 17



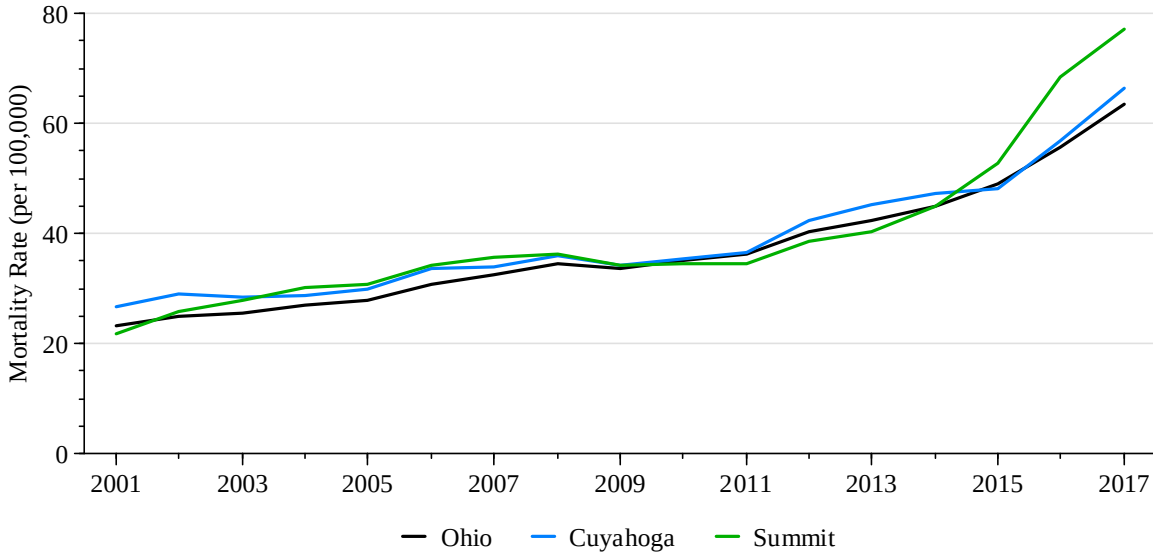
Sources: NVSS data from Plaintiffs' experts' backup materials.

E. Deaths of Despair

91. Exhibit 18 presents the evolution of what Case and Deaton call "deaths of despair" for the state of Ohio and for the counties of Cuyahoga and Summit. The exhibit shows a steady rise in all three series until the late 2000s, and then a period of faster growth starting in the early 2010s.

Exhibit 18

Ohio Mortality Rates Related to "Deaths of Despair"



Note: Deaths of despair include suicide, poisoning by drugs or alcohol, and alcoholic liver disease and cirrhosis, based on the ICD-10 codes used by Case and Deaton (2017). The above chart is based on a three-year rolling averages of these deaths.

Source: CDC Wonder.

VI. PROFESSORS CUTLER AND GRUBER DO NOT ESTABLISH A CAUSAL RELATIONSHIP BETWEEN THE ALLEGED MISCONDUCT AND ANY HARMS INCURRED BY SUMMIT AND CUYAHOGA COUNTIES

A. The Use of a Cross-Sectional Analysis as a Tool to Establish or Measure Any Harm to Summit and Cuyahoga Counties

92. The principal implicit causal chain in Plaintiffs' allegations is as follows: 1) physicians write prescriptions for opioids; 2) patients take their prescriptions to pharmacies to be filled; 3) anticipating the need to fill such prescriptions, pharmacies place orders for opioids (and typically have such products in stock); 4) distributors ship prescription opioids to the pharmacy in response to such orders; 5) the pharmacy fills the prescription; 6) the opioids are diverted for misuse and abuse; 7) some of the misuse and abuse leads to abuse of illicit

opioids, including heroin and fentanyl; and 8) the misuse and abuse of prescription and illicit opioids leads to increased criminal activity, addiction, child removals, and overdose deaths. The specific allegation with regards to Distributors is that Distributors should have identified those shipments that were likely to be diverted to misuse and abuse and should have reported and refused to fill the order.[85]

93. I understand from counsel for Distributors that Plaintiffs must establish that Summit and Cuyahoga Counties were harmed by the alleged misconduct of Distributors – that is, that some of the shipments that should allegedly have been reported or blocked, but were not, directly led to harms incurred by the two Counties. Plaintiffs' approach, however, does not trace out a causal chain, or the harms, specific for Summit and Cuyahoga Counties.

94. The general approach employed by Professor Cutler is to analyze the variation in mortality and shipments across counties and to use this variation to estimate the average relationship between shipments and mortality across all of the counties included in the model. This average relationship, which corresponds to the coefficient on shipments in Professor Cutler's model, does not necessarily apply to each individual county. Put differently, even if Professor Cutler had properly measured the average effect of shipments on mortality (and I explain below that he does not), that does not then mean that the coefficient would reliably measure the effect of shipments on mortality in every county, and that does not then mean that

[85] Summit Complaint at ¶¶ 566, 713; Cuyahoga Complaint at ¶¶ 534, 643. I understand that the expert report of Dr. Gregory Bell discusses the challenges to Distributors in identifying and blocking those shipments that were later diverted to misuse and abuse.

the coefficient from the model would measure the effect of shipments on mortality in Summit and Cuyahoga Counties in particular.[86]

B. Correlation Alone Does Not Establish Causation

95. In their reports, Professor Cutler and Professor Gruber claim that they have established a causal link between prescription-opioid shipments and opioid-related mortality. According to Professor Gruber, shipments of prescription opioids directly caused licit opioid mortality: "There is a direct, causal relationship between defendants' shipments of prescription opioids and the misuse and mortality from prescription opioids, with geographic areas that received higher volumes of per capita shipments of prescription opioids experiencing significantly higher rates of opioid related misuse and mortality, including [Summit and Cuyahoga Counties]."[87] Professor Gruber also claims that shipments of prescription opioids directly caused illicit mortality: "There is a direct, causal relationship between defendants' shipments of prescription opioids and the misuse of and mortality from illicit opioids, including heroin and fentanyl, which accelerated rapidly after 2010."[88]

96. Similarly, Professor Cutler claims that his direct model measures the causal effect of prescription-opioid shipments on opioid mortality: "The first [statistical] method is based on regression estimates of the relationship between changes over time in opioid mortality across different geographic areas and shipments of prescription opioids in those areas. This

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86 Alternative econometric approaches can be employed to focus on the experiences of a particular county. For example, a time series analysis measuring the relationship between the changes in mortality over time in a county to the prescription opioid shipments in that same county would produce an estimate based only on the experiences of that county.

87 Gruber Report at ¶ 16.

88 Gruber Report at ¶ 16.

regression is used to estimate the elevation in opioid-related mortality due to shipments of prescription opioids. This is referred to as the 'direct approach' because it specifically seeks to directly model the causal effect of shipments on mortality."[89]

97. Neither Professor Gruber nor Professor Cutler, however, have established the existence of a causal link between opioid shipments and mortality. At most, they have presented evidence of a correlation between the accumulated levels of prescription-opioid shipments and opioid-related mortality across 400 counties. Professor Cutler appeared to acknowledge this when he testified that regressions show correlation and that it is up to the researcher to put a causal interpretation on that correlation: "All regressions are by definition correlations. All that a regression does – I teach my classes this, so I preach it very widely – all that a regression does is gives you correlations, gives you very sophisticated correlations, but they're correlations. The causality comes from the interpretation of the individual who is using the results as to whether they want to provide a causal interpretation and, if so, make the argument that that's a – that that's a causal interpretation."[90]

98. Despite Professor Cutler's stated view that regressions simply give you correlations, he interprets his direct model as measuring a *causal* relationship between prescription opioid shipments and opioid-related mortality. Evidence suggests, however, that the correlation across counties between opioid shipments and opioid-related mortality is in part reflecting a third factor – namely, the extent to which the population in the counties are willing or motivated to misuse and abuse prescription opioids. The presence of this third factor is consistent with the "deaths of despair" literature that I discuss in Section III – that

89 Cutler Report at ¶ 26.

90 Cutler Deposition at 465:7-18.

"slow-acting forces" have created conditions of despair, and that these conditions contribute to the rise in morbidity and mortality, as well as in the engagement in risky behaviors such as alcohol and drug abuse.[91]

C. The Positive Coefficient on Shipments in Professor Cutler's Direct Model Is Not Evidence That Opioid Shipments Caused Opioid Mortality

99. Professor Cutler's direct model correlates the change in opioid-related mortality from 1993-1995 to 2009-2010 in 400 counties with average shipments per capita between 1997 and 2010 into those counties. He controls for some demographic characteristics of these counties – gender, age, race, ethnicity, and education – and for certain economic features – the unemployment rate, the employment-to-population ratio, the distribution of employment by sector, median household income, the poverty rate, and the county's population. The model includes both the levels of these variables at the starting point and the change in these variables between the beginning and ending time periods.

100. The starting point for establishing or measuring the relationship between the alleged misconduct and opioid-related mortality must be the allegedly "excess" shipments due to the alleged misconduct. Professor Cutler, however, does not seek to isolate the levels of excess shipments in each county and correlate those differences with differences in mortality. Instead, his cross-sectional approach measures the relationship between differences in shipments – irrespective of the source of those differences – and differences in opioid-related mortality. This fundamental flaw in Professor Cutler's approach means that the coefficient

91 Case and Deaton (2017) at pp. 433-434.

produced by his regression cannot be used to properly measure any harm attributable to the alleged misconduct.

101. Prescription opioid shipments are not themselves an exogenous variable. Rather, they are driven by factors such as the number of prescriptions written, which in turn are driven by factors such as the demand for opioids. Some of the demand for opioids is for legitimate pain treatment, and some of the demand is for opioid misuse and abuse.[92] By failing to isolate the variation in shipments attributable to the alleged misconduct, Professor Cutler builds a model that analyzes the variation in shipments from a wide number of sources, including variation that is unrelated to the alleged misconduct but correlated with opioid-related mortality. A model that measures the effect of changes to (variation in) shipments on opioid-related mortality, when the source of the variation analyzed is unrelated to the alleged misconduct, is not informative for establishing or measuring the impact of the alleged misconduct on any harms. In other words, Professor Cutler's model is not informative for answering the key question relevant to this litigation: To what extent did the alleged conduct lead to any opioid-related harms incurred by Summit and Cuyahoga Counties?

102. To demonstrate the error in Professor Cutler's interpretation of his regression coefficient, I perform a series of "tests" where I replace either the dependent variable (changes in opioid-related mortality) or the independent variable of interest (cumulative average shipments) with alternative variables that result in statistically significant estimates, but imply a different causal story.

92 The evidence I presented in Sections III and IV suggests that at least some of the demand for opioid misuse and abuse is driven by economic and sociological factors, and therefore would have prevailed absent the alleged misconduct.

1. Test 1: Professor Cutler's approach would purport to find illogical cause-and-effect relationships between shipments of prescription opioids and non-opioid "deaths of despair"

103. As I discussed above in Section IV, evidence and literature suggest an interconnected trend in fatal drug overdoses, alcohol-related disease, and suicide. These conditions are sometimes referred to as "deaths of despair."[93] Exhibit 19 shows one way of highlighting the presence of these underlying "despair" conditions that explains why Professor Cutler is incorrect in his opinion that shipments of prescription opioids attributable to the alleged conduct cause opioid-related mortality. The exhibit shows similarly why Professor Cutler's models do not establish that prescription opioids cause increases in mortality; following his arguments to their logical conclusion leads to nonsensical results.

104. Exhibit 19 reports the estimated coefficients and p-values for coefficients on shipments from regressions I estimated in which the right-hand-side variables are similar to those included by Professor Cutler in his direct model, but dependent variables are changes in measures of deaths of despair that are not directly related to opioid use or abuse.[94]

105. I measure the non-opioid-related deaths of despair using two methodologies. Both methodologies take as the starting point the definition of deaths of despair per Case and Deaton, which includes suicide, poisoning by drugs or alcohol, and alcoholic liver disease and cirrhosis. I determine the mortality rate in each county using the Case and Deaton deaths of despair metric, and then remove from the calculation those deaths that are caused by

93 *See* Case and Deaton (2017) at pp. 397-398.

94 The full results of the regressions shown in Exhibit 19 are in Exhibits C-1 and C-2 in Appendix C.

opioids.[95] The difference between the two methodologies is in how broad of a definition I use to define the set of opioid-related deaths that I exclude from the Case and Deaton metric. In Method 1, I exclude those deaths where the underlying cause of death is related to opioids.[96] In Method 2, I exclude any death where the underlying cause is drug-related and any opioid is included in the list of up to 20 additional "multiple" causes of death.[97] Method 2 likely understates the number of non-opioid related deaths of despair because I am excluding deaths where the deceased had multiple drugs in his or her system or other non-drug co-morbidities. Many of these deaths would likely have occurred in the absence of opioids. Moreover, I would expect the likelihood that a deceased person has opioids in his or her system at the time of death to be higher in areas with more shipments of prescription opioids. This means that, as a measure of non-opioid mortality, the metric based on Method 2 would tend to be too small in areas with high shipments.

106. For the models in Exhibit 19, the changes in the non-opioid deaths of despairs, and the changes in the economic and demographic control variables, are measured from 1999-2001 to 2009-2010, instead of from 1993-1995 to 2009-2010. I do this because the earliest year for which I have consistent data on the deaths of despair measures is 1999.[98]

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95 *See* Case and Deaton (2017) at pp. 397-398.

96 For example, in the first methodology I exclude from the deaths of despair calculation any death where the underlying cause is classified as ICD-10 code X42. ICD-10 code X42 is defined as "Accidental poisoning by and exposure to narcotics and psychodysleptics [hallucinogens], not elsewhere classified" (CDC Wonder). Because opioids are among the narcotics included in this category, I exclude from the non-opioid deaths of despair metric any death where the underlying cause is classified as ICD-10 code X42.

97 For the second approach, I use the deaths of despair in each county and year from CDC Wonder and then subtract the opioid-related mortality rate using the data provided in the backup materials to the expert reports of Professors Cutler and Gruber.

98 The source of the data for the dependent variables used in the analyses in Exhibit 19 are the compressed mortality files from CDC WONDER. Prior to 1999, the data are based on ICD-9 codes instead of ICD-10 codes. To avoid potential issues that could arise with using mortality data defined using a different set of codes, I begin my

Exhibit 19

Non-Opioid Deaths of Despair Are Correlated with But Not Causally Determined by Opioid Shipments

107. The first row of Exhibit 19 shows the coefficient on shipments from a model where I have replaced the dependent variable from Professor Cutler's regression with a different variable, non-opioid related drug mortality per the first methodology, but use the same right-hand-side variables as those in the replication of Professor Cutler's direct model and adjusting for the shorter time period. The estimation of the model produces a positive and statistically significant coefficient for the "average shipments per capita per day" variable.

108. The second row of Exhibit 19 shows the coefficient on shipments in a model where I have again replaced the dependent variable from Professor Cutler's regression with the measure of non-opioid deaths of despair based on the second approach, but use the same right-hand-side variables. The model also produces a positive and statistically significant coefficient on shipments. The magnitude of the coefficient is smaller than the coefficient in

analyses in 1999, which is sufficient to show the correlations between prescription opioid shipments and non-opioid related deaths of despair.

the first row, which reflects the fact that the second methodology is more likely than the first methodology to understate the number of non-opioid deaths of despair in areas with high numbers of shipments of prescription opioids.

109. The coefficients in Exhibit 19 show that Professor Cutler's model would find a statistically significant relationship between prescription opioid shipments and non-opioid deaths of despair. Applying Professor Cutler's causal interpretation to these estimates would imply that prescription opioid shipments caused non-opioid-related mortality. This interpretation does not make sense, and shows that Professor Cutler's model cannot be relied upon to establish causation. One would not conclude from the estimates in Exhibit 19 that shipments of prescription opioids cause non-opioid related deaths. Few if any non-opioid drug overdoses, non-opioid suicides, or alcohol-related deaths could plausibly be caused by shipments of prescription opioids. This result thus reinforces the conclusion that Professor Cutler's causal interpretation of his model is flawed.

110. What the model is telling us is that counties that received relatively high numbers of opioid shipments also had relatively high rates of "deaths of despair." The model suggests that some counties had, simultaneously, a relatively high demand for opioids, relatively large volumes of opioid shipments per capita, and relatively high "deaths of despair." The fact that all of these conditions prevailed at the same time does not justify a causal interpretation such as Professor Cutler's, according to which opioid shipments were the exogenous cause of any share of these negative health outcomes observed in these counties. A plausible driver of the correlation between prescription opioid shipments and non-opioid deaths of despair is that the despair conditions in these areas resulted in high levels of non-opioid suicides, non-opioid drug overdoses, and alcohol-related deaths. These despair conditions were also contributing

factors to the increased demand for opioid use, which led to an increase in the number of prescriptions, and an increase in the number of prescription opioid shipments.

2. Test 2: Professor Cutler's approach would purport to find illogical cause-and-effect relationships between prescription opioid shipments and cancer mortality

111. Cancer patients often use prescription opioids to help manage cancer-related pain.[99] I would therefore expect to find a correlation between areas with high prescription opioid shipments and high incidences of cancer. This correlation is driven by areas with high incidences of cancer mortality having a need for prescription opioids and other cancer-related treatments, physicians prescribing opioids in these areas to meet the needs of patients, and distributors shipping the opioids to pharmacies so that the pharmacies can fill those prescriptions.

112. Exhibit 20 follows a similar structure as Exhibit 19. The exhibit shows the coefficient and p-value from a model where the dependent variable is the change in cancer mortality from 1993-1995 to 2009-2010, and the right-hand-side variables are the same as those used in Professor Cutler's direct model. The estimation of this cancer mortality regression produces a positive coefficient on shipments that is statistically significant at the ten percent level. The model therefore suggests a correlation, as expected: physicians prescribe opioids to cancer patients to help those patients manage their pain, and distributors ship prescription opioids to pharmacies so the pharmacies can provide patients the prescribed

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99 The World Health Organization (WHO) outlines a "three-step 'ladder' for cancer pain relief in adults," and recommends opioids as treatment in the second and third steps: "If pain occurs, there should be prompt oral administration of drugs in the following order: nonopioids (aspirin and paracetamol); then, as necessary, mild opioids (codeine); then strong opioids such as morphine, until the patient is free of pain. To calm fears and anxiety, additional drugs – 'adjuvants' – should be used." ("WHO's cancer pain ladder for adults", World Health Organization, available at https://www.who.int/cancer/palliative/painladder/en/.) I understand that the expert report of Dr. Gregory Bell discusses in more detail the use of prescription opioids to provide pain relief to cancer patients.

opioids. One would not interpret the regression in 20 to suggest that shipments of prescription opioids cause cancer. A more sensible explanation is that high levels of prescriptions lead to high levels of opioid shipments in areas with high rates of cancer mortality.

Exhibit 20

Changes in Cancer Mortality Are Correlated with
But Not Causally Determined by Opioid Shipments

3. Test 3: Professor Cutler's approach would purport to find illogical cause-and-effect relationships between future shipments of prescription opioids and past mortality

113. As a third example of the danger in interpreting causality when a causal relationship does not exist, I regress the change in opioid-related mortality from 1993-1995 to 2009-2010 on cumulative average shipments between 2011 and 2016. Exhibit 21 shows the coefficient on (future) shipments from this regression. Prescription opioid shipments that have not yet occurred cannot cause increases in mortality, yet the coefficient on 2011-2016 shipments is positive and statistically significant.

Exhibit 21

Changes in Opioid Mortality Are Correlated with
But Not Causally Determined by Future Opioid Shipments

[redacted]

114. Professor Cutler of course does not claim to attribute past harms to future shipments, and he does not attempt to measure the "impact" of future shipments on past harms. It is not correct to interpret the observed relationship between 2011-2016 shipments and changes in 1993-1995 to 2009-2010 opioid mortality as evidence that future shipments cause past mortality. Similarly, it is not correct to interpret, as Professor Cutler does, the observed relationship between 1997-2010 shipments and changes in 1993-1995 to 2009-2010 opioid mortality, as evidence that an exogenous change in shipments leads to opioid-related mortality.

D. The Observed Correlation between Opioid Shipments and Opioid Mortality Does Not Mean That All High Shipment Counties Experienced High Opioid Mortality

1. Professor Gruber's graphical analysis

115. Professor Gruber's Figures I.18, I.19, and I.20 show the average prescription, illicit, and total mortality rates across counties in the top and bottom quartiles of the distribution (weighted by population) of opioid shipments.[100] The conclusion Professor Gruber draws from these figures is that the growth in opioid mortality, from both prescription and illicit opioids, had a strong relationship with per capita shipments of prescription opioids

100 Gruber Report at ¶¶ 84-87.

between 1997 and 2010, "with counties that received more shipments experiencing higher mortality rates."[101] I explained above that an observed correlation between prescription opioid shipments and opioid mortality does not mean that shipments caused mortality. An observed correlation also does not imply that counties that received high opioid shipments always had high levels of opioid-related mortality or that counties that received low opioid shipments always had low levels of opioid-related mortality. On the contrary, many counties in the top quartile of shipments had below-average mortality rates, and many counties in the bottom quartile of shipments had above average mortality rates.

116. Exhibit 22 shows the percentage of counties in the bottom shipments quartile with mortality rates that were higher than the population-weighted mean mortality rate across the 400 counties in Professor Gruber's sample.[102] The exhibit also shows the percentage of the population in the bottom shipments quartile that lives in counties with above-average mortality.

101 Gruber Report at ¶ 87.

102 I show in Exhibits 22 and 23 the same quartiles as Professor Gruber. Professor Gruber applies weights based on the county population. There are therefore different numbers of counties in each quartile, but each quartile has roughly the same number of people (per the populations of the counties in each quartile). His bottom-shipment quartile is comprised of 68 counties and his top-shipment quartile is comprised of 103 counties. I also apply population weights when determining the mean mortality rate across the 400 counties, which is consistent with how Professor Gruber calculates the mean mortality within the top and bottom quartiles.

Exhibit 22

Many Low-Shipment Counties Have Above-Average Opioid Mortality

Year	National Average Any Opioid Mortality	Share of Counties in **Bottom**-Shipment Quartile with Mortality Rates **Above** the National Average	
		Share of Counties	Share of Population
1999	4.4	15%	50%
2000	4.5	10%	23%
2001	4.7	18%	27%
2002	5.9	9%	22%
2003	6.2	12%	12%
2004	6.3	7%	3%
2005	6.8	15%	9%
2006	7.8	13%	17%
2007	8.2	10%	3%
2008	8.5	10%	3%
2009	8.7	25%	8%
2010	8.8	15%	5%
2011	9.6	19%	6%
2012	9.8	18%	5%
2013	10.3	16%	5%
2014	11.4	16%	5%
2015	13.0	19%	6%
2016	16.7	22%	20%

Source: Backup materials to the expert report of Professor Gruber.

117. The analysis in Exhibit 22 shows that, among counties with the lowest shipments, the share of counties with above-average mortality rates ranges from seven to 25 percent for each year from 1999 through 2016.[103] The percentage of the population living in these counties ranges from three to 50 percent, depending on the year. Thus, a number of counties with relatively few shipments have relatively high opioid mortality rates.

[103] Cuyahoga County is in the bottom second shipment quartile and Summit County is in the third shipment quartile. The opioid mortality rates in Cuyahoga and Summit are sometimes above and sometimes below the national average, depending on the year.

118. Exhibit 23 presents a similar analysis for the shipments in the top quartile. Here, I calculate the share of counties from the top quartile with below-average mortality, and the share of the population living in those counties.

Exhibit 23

Many High-Shipment Counties Have Below-Average Opioid Mortality

Year	National Average Any Opioid Mortality	Share of Counties in **Top**-Shipment Quartile with Mortality Rates **Below** the National Average	
		Share of Counties	Share of Population
1999	4.4	56%	48%
2000	4.5	42%	33%
2001	4.7	42%	32%
2002	5.9	41%	31%
2003	6.2	33%	25%
2004	6.3	32%	26%
2005	6.8	32%	24%
2006	7.8	29%	22%
2007	8.2	27%	20%
2008	8.5	23%	16%
2009	8.7	32%	22%
2010	8.8	20%	13%
2011	9.6	18%	16%
2012	9.8	31%	29%
2013	10.3	25%	22%
2014	11.4	28%	31%
2015	13.0	30%	31%
2016	16.7	34%	35%

Source: Backup materials to the expert report of Professor Gruber.

119. Exhibit 23 shows that, among counties with the highest shipments, the share of counties with below-average mortality ranged from 18 to 56 percent, and the percentage of the population in high-shipments counties living in counties with below-average mortality

rates ranges from 13 to 48 percent. The trends presented in Professor Gruber's charts hide the fact that many counties did not fit neatly the "predictions" of his analysis.[104]

2. Professor Cutler's statistical analysis

120. Professor Cutler also analyzes the correlation between prescription opioid shipments and opioid mortality. He does this through his direct model, which measures the correlation between cumulative average shipments of prescription opioids and changes in opioid mortality holding fixed the set of economic and demographic factors included in his model.

121. I explained above that Professor Cutler's direct model shows a correlation but does not establish that shipments caused mortality. An observed correlation also does not mean that all counties with high levels of cumulative average shipments had large increases in opioid-related mortality or that all counties with low levels of cumulative average shipments had low levels of opioid-related mortality.

122. Exhibit 24 shows the distribution of changes in opioid-related mortality (from 1993-1995 to 2009-2010) – relative to the average change in mortality across the 400 counties included in the sample – for counties in the top and bottom quartiles with respect to prescription-opioid shipments.[105] As shown in the exhibit, there are a number of counties in the bottom quartile of shipments that had changes in mortality above the national average

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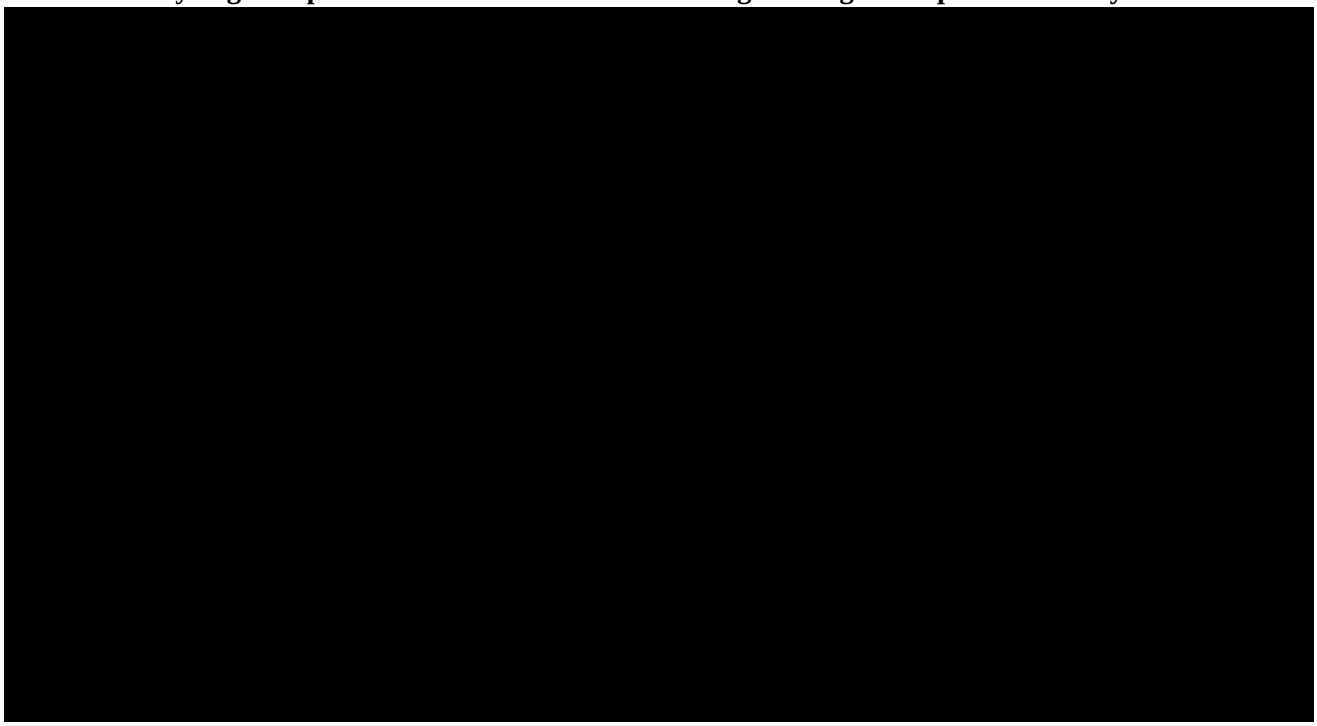
104 Exhibits C-5 and C-6 in Appendix C show similar analyses separately for licit and illicit opioid mortality. These exhibits show several low-shipment counties with above average licit and illicit opioid morality rates and several high-shipment counties with below average licit and illicit opioid morality rates.

105 In Exhibits 24 and 25 I include 100 counties in each quartile rather than weight by population when defining quartiles as Professor Gruber does in his Figures I.18, I.19, and I.20, and that I do in Exhibits 22 and 23. I do not weight by population to be consistent with Professor Cutler's regression approach, which gives each county equal weight.

(blue bars in the figure on the left), and several counties in the top quartile of shipments that had changes in mortality below the national average (red bars in the figure on the right).

Exhibit 24

Many Low-Shipment Counties Have Above-Average Changes in Opioid Mortality and Many High-Shipment Counties Have Below-Average Changes in Opioid Mortality



123. Exhibit 25 shows the distribution of adjusted changes in opioid-related mortality relative to the national average for counties in the top and bottom quartiles with respect to prescription-opioid shipments. In this exhibit, the changes in opioid-related mortality rates have been adjusted to account for the same demographic and economic factors that Professor Cutler includes as controls in his direct regression model. He claims that these control variables should capture a wide variety of factors other than prescription-opioid shipments

that affect opioid mortality.[106] The exhibit shows that, even after adjusting for these factors, there are still counties with relatively high levels of shipments that have relatively low levels of adjusted changes in opioid-related mortality and counties with relatively low levels of shipments that have relatively high levels of adjusted changes in opioid-related mortality.[107]

Exhibit 25

Many Low-Shipment Counties Have Above-Average Adjusted Changes in Opioid Mortality and Many High-Shipment Counties Have Below-Average Adjusted Changes in Opioid Mortality

Adjusting for Economic and Demographic Characteristics of Each County

VII. PROFESSOR CUTLER DOES NOT RELIABLY ESTIMATE THE SHARE OF ANY OPIOID-RELATED HARMS ATTRIBUTABLE TO SHIPMENTS

106 Cutler Report at ¶ 77: "As discussed further below, the regression analysis accounts for a wide variety of factors that potentially affect opioid mortality including the demographic characteristics of the population and various measures of economic opportunity."

107 In the analyses presented in Exhibits 24 and 25, Cuyahoga is in the bottom quartile of prescription opioid shipments and it has a below-average change in mortality rate and a below-average adjusted change in mortality rate. Summit County is in the third shipments quartile and it has an above-average change in mortality rate and a below average change in adjusted mortality rate.

A. Professor Cutler's Two Approaches

124. Professor Cutler uses two approaches to estimate the share of any opioid-related harms attributable to shipments. In Approach 1, he uses his direct model of opioid mortality along with an "indirect" model of *illicit* opioid mortality (which I discuss in Section VII.C, below). He describes this approach as follows:

> *Approach 1 estimates the impact of defendants' misconduct on opioid mortality in three parts:*
>
> *1. The share of opioid-related mortality from 2006 to 2010 that is attributable to defendants' misconduct is calculated using the results of the direct regression model and incorporating the estimates of the share of prescription opioid shipments due to defendants' misconduct calculated by Prof. Rosenthal;*
>
> *2. The share of licit opioid related mortality from 2011 to 2016 that is attributable to defendants' misconduct is calculated using the results of the direct regression model and incorporating the estimates of prescription opioid shipments due to defendants' misconduct calculated by Prof. Rosenthal; and*
>
> *3. The share of deaths due to illicit opioids from 2011 to 2016 that is attributable to defendants' misconduct is calculated using an indirect regression model that estimates the increase in illicit opioid mortality that is unexplained by social and demographic factors relative to the pre 2011 baseline.*[108]

125. In Approach 2, Professor Cutler uses only an indirect model, which is a different indirect model than the one used in Approach 1:

> *Approach 2 calculates the share of opioid mortality due to defendant's shipments attributable to misconduct based on the indirect regression model that estimates the relationship between opioid mortality and the economic and demographic characteristics of counties over the 1993-95 time period.*[109]

126. Both approaches contain fatal flaws that make his estimates unreliable.

B. Professor Cutler's "Direct" Model Does Not Provide a Measure of the Relationship

108 Cutler Report at ¶ 102.

109 Cutler Report at ¶ 116.

between Shipments and Mortality that Can Be Used to Properly Measure the Impact of the Alleged Misconduct on Any Harms to Summit and Cuyahoga Counties

1. Using shipments as a proxy for consumption is not informative for estimating the effect of the alleged misconduct on harms

127. Professor Cutler claims to measure the share of alleged opioid harm attributable to shipments. As I explained above, however, his model does not measure the effect of changes in shipments holding constant the demand for opioids, including the demand for opioid misuse and abuse. As such, the coefficient in Professor Cutler's model cannot be used to establish causality, and it cannot be used to properly measure the effect of the alleged misconduct on opioid mortality.

128. Professor Cutler also claims in his report, and testified during his deposition, that in his direct model he is using shipments of prescription opioids as a proxy for the consumption of opioids.[110] By characterizing his model as measuring the relationship between "consumption" and mortality, Professor Cutler appears to acknowledge that his proxy for consumption is reflecting factors other than the supply of opioids, including factors other than the Distributors' shipment decisions (which are in turn driven by prescriptions written by physicians).

129. Even if Professor Cutler were able to establish that shipments are a proxy for consumption, an empirical finding of a relationship between opioid consumption and opioid-related mortality (i.e., mortality due to opioid consumption) is not surprising. A person cannot overdose from opioids without having first consumed opioids, so it would be unusual

[110] Cutler Report at ¶ 74: "However, data on consumption in an area are not available, so data on shipments to the area are used as a proxy for consumption." *See, also,* Cutler Deposition at 325:22-326:17.

as a general matter to find higher rates of opioid mortality in areas with low levels of opioid consumption. The relationship between consumption and mortality, however, is not informative for understanding or measuring an effect of the alleged conduct at issue in this litigation.

130. As I discussed above in Section VI, under Plaintiffs' experts' methodology, Professor Cutler must ensure that the estimated relationship between opioid shipments and any opioid-related harm is a relationship between the aspect of shipments that the alleged misconduct would affect, and not elements of the demand for opioids (including the demand for opioid misuse and abuse) that are not related to the alleged misconduct. By failing to identify and isolate aspects of opioid consumption affected by the alleged misconduct, Professor Cutler has failed to estimate an impact on mortality that can be used to properly estimate any harms attributable to alleged misconduct.

131. Neither Professor Cutler nor Professor Rosenthal identifies a set of shipments that led to harm in any individual county. Rather, Professor Cutler assumes that any reduction in shipments would reduce "harms." His analysis implies that blocking *all* prescription opioid shipments starting in 1997 would have reduced opioid-related harms by between 49.2 percent (in 2006) and 90.7 percent (in 2016).[111] The elimination of all shipments, however, would mean that patients who need pain medication would not have access to it. Professor Cutler does not factor into his analysis the negative outcomes associated with reducing opioid

[111] *See* Cutler Report Appendix III.I at Table I.4, Column M.

shipments, including the negative outcomes associated with eliminating opioid shipments altogether.[112]

2. Professor Cutler does not control for all of the factors correlated with shipments that influence opioid mortality

132. Professor Cutler includes in his direct model a set of economic and demographic factors "to ensure that estimates of the relationship between shipments and mortality properly control for other factors that might affect opioid mortality."[113] In order for his coefficient on shipments to be used to estimate the share of mortality attributable to the alleged misconduct, his set of control variables would have to capture the aspects of the demand for opioids that are not related to the alleged misconduct. If any factors not captured by Professor Cutler's controls affect mortality and are also correlated with his measure of shipments, Professor Cutler would wrongly attribute the effect of those factors to shipments which, in economic terms, means that his coefficient would be biased.

133. One set of factors that likely affect opioid mortality, and that are unlikely to be completely captured by the economic and demographic factors included in Professor Cutler's

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[112] I understand that the expert report of Dr. Gregory Bell discusses in more detail the efficacy of prescription opioids in treating and managing pain. Professor Cutler testified that he is not looking at the benefits to the individual or to society in his analysis, and that he is only looking at harms to the governments of the counties. (Cutler Deposition at 55:15-15-60:23, 220:19-221:10.) He also testified that a benefit of prescription opioids to the county would show up in his model as a reduction in mortality. (Cutler Deposition at 221:18-23.) Professor Cutler, however, does not take into account in his analyses that eliminating prescription opioids as a treatment for pain relief could harm the counties in a way that would not be reflected as reduction in opioid-related mortality.

[113] Cutler Report at ¶ 86. I understand that the expert report of Dr. Gregory Bell discusses a number of factors not directly captured by the control variables in Professor Cutler's direct model, that contribute to opioid mortality and to other opioid-related harms, such as addiction, for which Professor Cutler uses mortality as a proxy. Mental health, for example, is sometimes cited as a contributing factor to substance abuse. *See, for example,* "Dual Diagnosis", *National Alliance on Mental Illness*, available at https://www.nami.org/Learn-More/Mental-Health-Conditions/Related-Conditions/Dual-Diagnosis.

model, are the "despair" conditions that I discussed above in Section IV. Imagine a simple model in which the true relationship is:

$$y = \alpha + \beta_1 x + \beta_2 z + \varepsilon \quad [1]$$

where y represents Professor Cutler's measure of mortality, x represents shipments, z represents an omitted variable that measures, for example, the level of despair, and ε represents the error term. If the measure of despair is also correlated with shipments, we can model that similarly:

$$x = \gamma + \delta z + \nu \quad [2]$$

Professor Cutler claims that he is estimating β_1, but is using the following equation:

$$y = \alpha + \tilde{\beta}_1 x + \xi \quad [3]$$

where in this case I use $\tilde{\beta}_1$ to refer to the biased estimator, and ξ represents Professor Cutler's error term which includes variation due to variables that Professor Cutler omits from his regression (in this simple illustration, $\xi = \beta_2 z + \varepsilon$). From [1] and [2] above we can write:

$$y = \alpha + \beta_1 x + \frac{\beta_2}{\delta}(x - \gamma - \nu) + \varepsilon$$

Rearranging the terms yields:

$$y = \left(\alpha - \frac{\beta_2}{\delta}\gamma\right) + (\beta_1 + \frac{\beta_2}{\delta})x + (\varepsilon - \frac{\beta_2}{\delta}\nu) \quad [4]$$

Comparing [3] and [4] we see that Professor Cutler is in fact estimating $\tilde{\beta}_1 = \beta_1 + \frac{\beta_2}{\delta}$, where the bias is indicated by $\frac{\beta_2}{\delta}$. If despair is positively correlated with shipments, and it is also positively correlated with mortality, then both β_2 and δ are positive which means that Professor Cutler is overstating any relationship that may exist between shipments of prescription opioids and mortality.

134. To demonstrate how these conditions would affect Professor Cutler's estimates, I estimated a version of Professor Cutler's direct model in which I included, as an additional control, two measures of non-opioid-related deaths of despair. These are the same two measures that I analyzed in Section VI.C.1 to demonstrate that Professor Cutler's direct model does not establish a causal relationship between prescription opioid shipments and opioid mortality. Here, I use these as proxies for the "despair" conditions that prevailed in many areas of the country and that I discussed in Section IV.

135. Exhibit 26 shows how the inclusion of each these proxies for despair – which I note are not the only addition controls that would be required to reliably estimate a causal relationship between shipments attributable to the alleged misconduct and opioid-related mortality – reduces the magnitude of his shipments coefficient.[114] The exhibit shows the percent reduction in coefficient on shipments relative the coefficient produced by a model similar to Professor Cutler's direct model that does not include the non-opioid "deaths of despair" control. I explained in Section VI.C.1 that the non-opioid deaths of despair measure calculated using Method 1 potentially includes some opioid-related comorbidity, and the measure calculated using Method 2 potentially excludes deaths that would have occurred even in the absence of opioids. Exhibit 26 shows that the inclusion of the Method 1 metric reduces the coefficient by 80 percent and the inclusion of the Method 2 metric reduces the coefficient by 47 percent.

[114] The full set of results from these regressions are in Exhibit C-7 and C-8 of Appendix C. The time period covered by these regressions differs somewhat from Professor Cutler's original regression, so I also include a version of his regression restricted to the same time period as Exhibits C-9 and C-10 of Appendix C.

Exhibit 26

Controlling for Proxies for Despair Conditions
Reduces Professor Cutler's Estimates of Impact

[redacted]

136. Professor Cutler testified that he controlled for all of the factors that he could think of that would pick up "malaise" (the concept that I refer to as "despair").[115] The analyses in Exhibit 26 show, however, that even simple proxies for despair that were available to Professor Cutler can have a large effect on his results. More generally, the analyses in Exhibit 26 show that it is wrong to interpret Professor Cutler's regression coefficient of [redacted] as measuring the causal impact of shipments on mortality. Rather, the coefficient reflects the effect of factors not included in his model that are correlated with both prescriptions opioid shipments and opioid mortality – his regression analyses establish a correlation only.

[115] *See* Cutler Deposition at 305:11-17: "In my analysis I controlled for as many factors as we could possibly get any information on. So it's always possible that one would always want to include additional data if one had it, but we took account of everything that we could think of that would pick up the malaise." *See, also,* Deposition of Jonathan Gruber, April 25, 2019 ("Gruber Deposition"), at 130:2-6: "I did perform a number of analyses and considerations regarding the third possibility that there is an omitted factor causing both [the increase in opioid shipments and the increase in opioid mortality]."

3. Shipments of prescription opioids are driven by prescriptions

137. When discussing the estimates from his direct model, Professor Cutler writes: "The results indicate that, all else equal, each unit increase in shipments between 1997 and 2010 (measured in MME per capita per day) raises the mortality rate by [redacted] deaths per 100,000, an increase of more than 160 percent over the average rate in the base period."[116] This statement implies that opioid shipments functioned as an exogenous variable that, in and of themselves, generated negative outcomes, including opioid abuse and opioid-related mortality. Shipments are not exogenous. The causal chain that leads to shipments includes physicians writing prescriptions, which causes pharmacies to place orders to fill prescriptions, which leads to distributors shipping prescription opioids in response to orders.[117]

138. Exhibit 16 shows the trends in shipments and prescriptions over time for Cuyahoga and Summit counties.[118] The exhibit shows that the trends in prescriptions and

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[116] Cutler Report at ¶ 92. In the estimation of his direct model, Professor Cutler excludes from the data four counties with high levels of shipments. If I estimate his model including the four counties Professor Cutler excluded, the estimated coefficient for the relationship between opioid shipments and mortality is [redacted]. By excluding these four counties with large numbers of shipments, Professor increases his coefficient by [redacted]). *See* Exhibit C-11 in Appendix C. Professor Cutler testified that he excluded these counties because he suspected that they had high levels of "transshipments" (shipments of prescription opioids to a county that were consumed by people who live in other counties) (*see* Cutler Deposition at 457:19-458:7), but acknowledged that he did not have any direct evidence of transshipments. (Cutler Deposition at 458:15-20: "What we did was we excluded the four counties that were very appreciable outliers in the shipments per capita, which my theory is that there was a good deal of transshipment, but I do not have a direct estimate of that.")

[117] Professor Gruber acknowledges in his report that prescription activity drives shipments. *See*, Gruber Deposition at 441:4-18. *See, also,* Gruber Report at ¶ 74. Professor Cutler testified that prescriptions are correlated with shipments. *See* Cutler Deposition at 643:22-644:3: "The data that we have from Professor Rosenthal's report as well as – I believe other data in the literature, but certainly in Professor Rosenthal's report is that prescriptions track shipments very well over time." *See, also,* Cutler Deposition p. 646:8-9: "Certainly in the aggregate [prescriptions and shipments] are very highly correlated." *See, also,* Cutler Report ¶ 83: "However, the issue affects less than [redacted] percent of the drug shipments in ARCOS, and the correlation between shipments of Schedule II opioids from IQVIA and shipments of all opioids from ARCOS is [redacted] implying the issue is only minimal importance."

[118] For this analysis, I rely on data from IQVIA used in the analyses presented in the expert report of Dr. Gregory Bell. I understand that these data have limitations. For example, they are based on a sample and therefore do not include the entire universe of prescriptions.

shipments trends track each other closely; the trends do not suggest an increase in shipments unrelated to prescriptions in either county.

139. Taking account of the fact that prescriptions written by physicians drive shipments, then Professor Cutler's direct method can be expected to show that prescriptions are correlated with opioid-related mortality, and one could employ a similar methodology as Professor Cutler's to arrive at an estimate of "impact" attributable to all prescriptions.[119] If I were to apply to these results the same interpretation that Professor Cutler applies to his direct model, I would conclude that opioid-related mortality is causally determined by prescriptions.[120]

140. Exhibit 27 shows the prescription and shipment trends at the national level. In this chart, I also include the DEA prescription opioid quotas. Not only do shipments and prescriptions track each other well over time, but the DEA quotas also follow a similar pattern, which suggests that the changes in shipments over time were aligned with both prescribing patterns and with DEA regulations.

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119 When Professor Cutler was asked at deposition if a model similar to his direct model could be used to show a relationship between opioid mortality and prescriptions Professor Cutler testified that "[t]here are not data on prescriptions that can be used to test this" because the prescription data are not measured in MME. (*See* Cutler Deposition at 521:19-522:20.) The IQVIA data that I use in Exhibit 16 however, provide a measure of the number of prescriptions in MME per capita per day, and are available at the ZIP Code level.

120 Professor Cutler testified that prescriptions are "also an outcome of the misconduct on the part of the defendants" (Cutler Deposition at 561:18-19), but he does not explain how the Distributors actions would lead to increased opioid prescriptions.

Exhibit 27

4. Professor Cutler disregards that, as his estimates go further back in time, the fewer years there are for shipments to accumulate.

141. Independent of the errors discussed above, Profess Cutler's analysis overestimates the magnitude of the impact when applying his direct regression estimates to earlier years. Professor Cutler estimates the relationship between cumulative shipments and mortality using the increase in mortality from 1993-1995 to 2009-2010 and the total accumulated opioid shipments from 1997 through 2010 expressed as an average across years. Professor Cutler implicitly assumes that the same estimated coefficient (effect) applies to several years before 2010. Specifically, in his Table I.1, he applies the same coefficient [redacted] to each year between 2006 and 2010. This approach is problematic.

142. As his measure of shipments, Professor Cutler uses the cumulative average across years because such an approach, he argues, "recognizes that shipments attributable to defendants' misconduct in one year can affect misuse and addiction in later years."[121] He then assumes that the estimated relationship between shipments and mortality holds for earlier years as well,[122] even though his theory is that it is the accumulation of shipments over time that leads to mortality.[123]

143. The error in Professor Cutler's methodology is most readily seen by changing his independent variable from cumulative average shipments to cumulative shipments – that is, by multiplying his shipments measure by 14, the number of years over which the average is calculated. Doing this does not change his regression in a fundamental way: the independent variable of interest (shipments) is increased by a factor of 14, and the estimated coefficient is correspondingly reduced by the same magnitude [redacted][124] The other regression outputs – including the R-squared of the model and coefficients on the other control variables are unaffected by this change.

144. Following Professor Cutler's approach, I use this (recalculated) coefficient to estimate the purported impact of opioid shipments on opioid-related mortality: I multiply

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121 Cutler Report at ¶ 105.

122 Cutler Report at ¶ 105, footnote 77: "Note that this approach assumes that the relationship between cumulative average shipments and mortality holds in the data every year."

123 Cutler Report at ¶¶ 26-27.

124 The full set of results from this regression are reported in Exhibit C-12 in Appendix C. *See, also,* Cutler Deposition at 539:12-540:14: "The cumulative average shipments is just dividing by the number of years. So in the regression it would not have affected things at all; that is, the estimates would have been that the R-squared of the model would have been exactly the same. The coefficients on all variables other than the shipments would have been the same. And the shipments variable would just be, you know, 13 times smaller[.]" (Professor Cutler testified that the coefficient would be 13 times smaller, but he appears to have miscounted the years. The number of years is 14 (1997 to 2010 including 1997 and 2010), so the coefficient is 14 times smaller.)

cumulative shipments from 1997 through 2010 by the estimated coefficient [redacted] Exhibit 28 shows that this does not change Professor Cutler's estimated impact *for the year 2010*. The coefficient is reduced by a factor of 14 to account for the fact that shipments are now expressed as total shipments across 14 years (1997-2010) rather than as an annual average, and the measure of shipments to which the coefficient is applied is multiplied by 14 [redacted] The estimated impact is the same as that presented in Professor Cutler's report [redacted]

Exhibit 28

Professor Cutler's Methodology Inflates His Impact Estimates in Early Years

[redacted]

145. Exhibit 28 also shows, however, that the calculations in Professor Cutler's report inflate the estimated impact *for all years prior to 2010*. This is so because in years prior to 2010 fewer shipments have accumulated. Exhibit 28 shows that, for years 2006 through 2009, the estimated impact under Professor Cutler's model and theory is lower than the impact he presents in his expert report. This leads him to overestimate the "impact" calculated from his own model for years prior to 2010. The largest difference is in 2006, at which point in time there have been the fewest years for shipments to accumulate. The difference is substantial as Professor Cutler's estimated impact in 2006 is 40 percent higher

than the impact that results from properly applying Professor Cutler's own theory to the estimation results.

C. Professor Cutler's "Indirect" Models Do Not Measure the Relationship between Prescription Opioid Shipments and Alleged Opioid-Related Harms

146. Professor Cutler's indirect model used in Approach 1 correlates the log of mortality related to illicit opioids in 2008-2010 with demographic and economic variables in that same period. He then uses in Approach 1 the coefficients obtained from this regression, and information on the right-hand-side covariates for 2011 through 2016, to forecast the path of illicit-opioid mortality between 2011 and 2016. He claims that the difference between actual illicit-opioid mortality and this "projected" illicit-opioid mortality reflects the incremental impact of opioid shipments on mortality in each year 2011 through 2016 (that is, the impact on top of the impact that he has already estimated for 2010 using his direct model).[125]

147. Professor Cutler's indirect model used in Approach 2 correlates the log of mortality related to both licit and illicit opioids in 1993-1995 with the demographics and economic variables from that same period. He uses the coefficients obtained from this regression, and information on the right-hand-side covariates for 2006-2016, to forecast the path of all opioid mortality between 2006 and 2016. He claims that the difference between actual opioid mortality and the projected opioid mortality reflects the impact of opioid

[125] Cutler Report at ¶¶ 111-114.

shipments on opioid mortality (and ultimately to the various "harms" attributable to opioids).[126]

148. Professor Cutler's indirect models do not estimate the relationship between shipments of prescription opioids and opioid-related mortality. Rather, his indirect approach models mortality using a set of economic and demographic characteristics and simply assumes that anything not explained by the model is attributable to opioid shipments.

1. Professor Cutler's decision not to use his direct model for the 2011-2016 period acknowledges that there is no consistent relationship between prescription opioid shipments and opioid mortality

149. Professor Cutler argues that "the existence and widespread dependence on opioids, coupled with a decline in the available supply of prescription opioids after 2010, led to an increased demand for illicit opioids, first heroin and later fentanyl."[127] He claims that it is necessary to use an indirect approach – as opposed to a direct approach – for the 2011-2016 period because there were several changes in the marketplace that reduced the supply of prescription opioids: "Between 2010 and 2016, prescription (i.e. licit) opioid shipments fell. There were many causes of this including but not limited to: OxyContin was reformulated in an attempt to make it more difficult to abuse; medical organizations began warning against excessive prescribing of opioids; and federal and state governments began expanding

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126 *See* Cutler Report at ¶ 97: "[D]eaths due to illicit opioid use increased dramatically after 2010, but projections of the average but-for illicit mortality rate based on the 2008-10 regression indicate that illicit mortality would have fallen in the absence of the decline in shipments of prescription opioids, and the increased demand for illicit opioids after that time." *See, also*, Cutler Report at ¶ 100: "[O]pioid mortality increased dramatically after 1995, but projections of the average 'but-for' opioid-related mortality on the 1993-95 indirect regression model indicate that opioid mortality generally would have been stable in the absence of the defendants' actions."

127 Cutler Report at ¶ 51.

enforcement against 'pill mills' and other forms of diversion of prescription opioids for non-medical use. The FDA pointed to these various factors in their review of whether Purdue's reformulated OxyContin reduced abuse of the drug."[128] All of these changes, Professor Cutler argues, occurred around 2010: "In short, the nature of the opioid crisis changed around 2010. This resulted in a shift in the relationship between shipments of prescription opioids and mortality that has been widely recognized in the economic literature."[129]

150. Professor Cutler assumes that, in years up to 2010, shipments causally affect licit- and illicit-opioid mortality. In his view, in those years, more prescription opioid shipments led to more opioid-related mortality, and fewer prescription opioid shipments led to less mortality. Under Professor Cutler's theory, however, illicit-opioid mortality increased after 2010 because prescription-opioid shipments *decreased*, which led users to switch to illicit opioids. Professor Cutler does not explain this fundamental contradiction embedded in his model, namely that a *decrease* in shipments led to the rise in illicit-opioid mortality after 2010, whereas before 2010 it was an *increase* in shipments that, in his view, led to a rise in illicit-opioid mortality. Professor Cutler cannot have it both ways. If his theory is that a fall in shipments after 2010 led to a rise in illicit-opioid mortality, then by logical consequence, a rise in shipments before 2010 should have led to a decline in illicit-opioid mortality. If, on the other hand, fewer shipments of prescription opioids prior to 2010 would lead to an decrease in illicit-opioid mortality, as Professor Cutler claims to be the case when measures the impact for the 2006 to 2010 period, then fewer shipments should also reduce illicit-opioid mortality after 2010.

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128 Cutler Report at ¶ 52.

129 Cutler Report at ¶ 55.

2. Professor Cutler's indirect model of illicit mortality wrongly attributes any change to the marketplace after 2010 to accumulated shipments of prescription opioids

151. In his indirect model of illicit mortality, Professor Cutler attributes *all* of the changes in the marketplace that led to an increase in illicit mortality after 2010 to opioid shipments.[130] This includes the change in the availability of, prices of, and risks associated with illicit opioids.[131] Professor Cutler acknowledges this in this report. He writes: "The indirect regression attributes the entirety of the unexplained opioid-related mortality to shipments. To the extent that other factors not modelled in the 'baseline' regression contributed to increases in opioid mortality, the indirect approach has the potential to overstate the impact of defendants' actions."[132]

152. Professor Cutler cites several papers in support of his use of an indirect or "residual" model to measure "economic impact."[133] However, for the most part, these papers discuss technological change – a term generally used in economics to refer to an increase in

130 Professor Cutler testified that, in using his indirect model, he only attributes to the conduct those changes to the marketplace that are not captured by the economic and demographic characteristics that he includes as controls in his model. (Cutler Deposition at 343:18-344:1: "Q. And to be clear, regardless of what the policies were that resulted in increased use of illicit opioids after 2010, your indirect model attributes all of the harm associated with those reductions to the defendants, correct? A. No. It attributes the harm that cannot be explained by the other social and demographics economic changes.") But his economic and demographic factors imply that illicit opioid mortality should have *declined* from 2011 to 2016, which means that Professor Cutler attributes *more* than 100 percent of the increase in illicit mortality to shipments of prescription opioids. In addition, when he estimates his impact percentages, he assumes that some of the illicit mortality in his baseline period was also attributable to shipments of prescription opioids, so the but-for mortality used in his calculations of impact are even lower (which makes the impact higher) than what he shows in his Figure III.5. (*See* Cutler Report Table I.3.)

131 The indirect model that Professor Cutler uses in Approach 2 models all opioid mortality using the years 1993-1995 as the base period. In this model, any changes in the marketplace for illicit or licit opioids from 1996 through 2016 not captured by the economic and demographic factors in the model are attributed to the misconduct. (*See* Cutler Report Figure III.6, ¶¶ 100, 112.)

132 Cutler Report at ¶ 78, footnote 53.

133 Cutler Report at ¶ 80.

output without increased inputs. In one article, economist Robert Solow is discussing an aggregate production function, which is a function of capital and labor units, and a catchall "*t*" to allow for technical change, about which he writes: "It will be seen that I am using the phrase 'technical change' as a short- hand expression for *any kind of shift* in the production function. Thus slowdowns, speed- ups, improvements in the education of the labor force, and all sorts of things will appear as 'technical change.'"[134]

153. Professor Cutler also cites a paper by Joseph Newhouse discussing reasons for increasing medical costs.[135] Newhouse explores several potential explanations for increasing medical costs, then writes: "[b]ecause of the problem in measuring productivity, it is hard to know how much of the increase all the above factors can account for ... I believe the bulk of the residual increase is attributable to technological change, or what might loosely be called the march of science and the increased capabilities of medicine."[136] He then goes on to list several examples of new medical products and procedures as examples of technological change, but adds: "[t]rying to attribute a residual to a specific factor is an inherently frustrating exercise, and the best I can do to support my argument that much of the residual is attributable to the new capabilities of medicine … is to buttress it with data that I believe are consistent with it."[137] Unlike Professor Cutler, Newhouse attempts to do so; Professor Cutler

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134 Solow, Robert M., "Technical Change and the Aggregate Production Function," *The Review of Economics and Statistics vol. 39 No, 3,* August 1957, pp. 312-320, at p. 312.

135 "This method also formed the basis for a widely cited study by Joseph Newhouse arguing that technical change was the primary driver of medical care costs over time." Cutler Report at ¶ 80.

136 Newhouse, Joseph P., "Medical Care costs: How Much Welfare Loss?" *Journal of Economic Perspectives Vol. 6 No. 3,* Summer 1992, pp. 3-21 ("Newhouse (1992)"), at p. 11.

137 Newhouse (1992) at p. 11.

makes no such effort – he simply assumes that the entirety of the residual is attributable to the alleged misconduct.

154. These are not examples of economists conducting analyses of economic impact in the context of estimating a causal relationship between specific factors. Claiming that this literature justifies attributing all of the changes in the marketplace that led to an increase in illicit mortality after 2010 is a mischaracterization of the literature; technological change is inherently difficult to quantify. Plaintiffs, on the other hand, claim to have quantified the alleged misconduct – they should then quantify the relationship between the alleged misconduct and any alleged impact of that conduct, rather than simply assume that all of the changes that they cannot explain are due to the conduct.

155. Professor Cutler disregards the changes in the availability of illicit opioids that contributed to the increase in the use of illicit opioids after 2010. Professor Gruber acknowledges that fentanyl is a "low-cost and high potency alternative to heroin."[138] He points out that fentanyl is more dangerous, that it is more profitable to drug dealers, and that its prevalence increased after 2010.[139] Neither he nor Professor Cutler, however, account for the fact that the changes in the characteristics or prices of illicit opioids before and after 2010 could have led to increased illicit-opioid mortality even in the absence of the alleged misconduct.[140] Indeed, as discussed above, opioid abuse (including prescription opioid abuse)

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138 Gruber Report at ¶ 58.

139 Gruber Report at ¶¶ 55-56.

140 Professor Cutler testified that the introduction of fentanyl was due to the defendants' conduct because the conduct created "thicker markets for illegal opioids." (*See* Cutler Deposition at 365:21-366:14.) Professor Cutler, however, has not shown that the defendants' conduct led to the thickening of markets, or that thick markets led to the introduction of fentanyl. As discussed further below, he has not attempted to measure or characterize the purported thickness of illicit drugs markets and admitted in his deposition that he has no data of the type that would

remained relatively flat or declined over the relevant period, but opioid mortality increased, as would be expected if increases in mortality were caused by the higher prevalence of fentanyl, carfentanil, and other synthetic opioids.

156. Neither Professor Cutler nor Professor Gruber provide statistical evidence that *any* of the changes that led to an increase in mortality related to illicit opioids after 2010 were driven by prescription-opioid shipments, let alone *all* of the changes. Thus, the conclusion I draw is that his indirect model not only has the potential to overstate the impact of the alleged misconduct but also is highly likely to do so.

3. Professor Cutler wrongly implies that all of the changes to regulations around prescription opioids occurred in 2010

157. Professor Cutler's indirect model also relies on the assumption that the relationship between opioid shipments and opioid-related mortality changed radically in or around 2010. He disregards the fact that some of these changes occurred gradually over a multi-year period, rather than all at once in 2010. For example, Professor Cutler cites Prescription Drug Monitoring Programs (PDMPs) as a change that affected the 2011-2016 marketplace.[141] States, however, implemented PDMPs at different points in time over a long period of time, with some states adopting PDMPs in 1990s and others in years after 2010. In addition, the PDMPs were not always immediately accessible to prescribing physicians, pharmacists, and members of law enforcement. Exhibit 29 shows over time the number of states (including the District of Columbia) with a PDMP, and the number with a PDMP that

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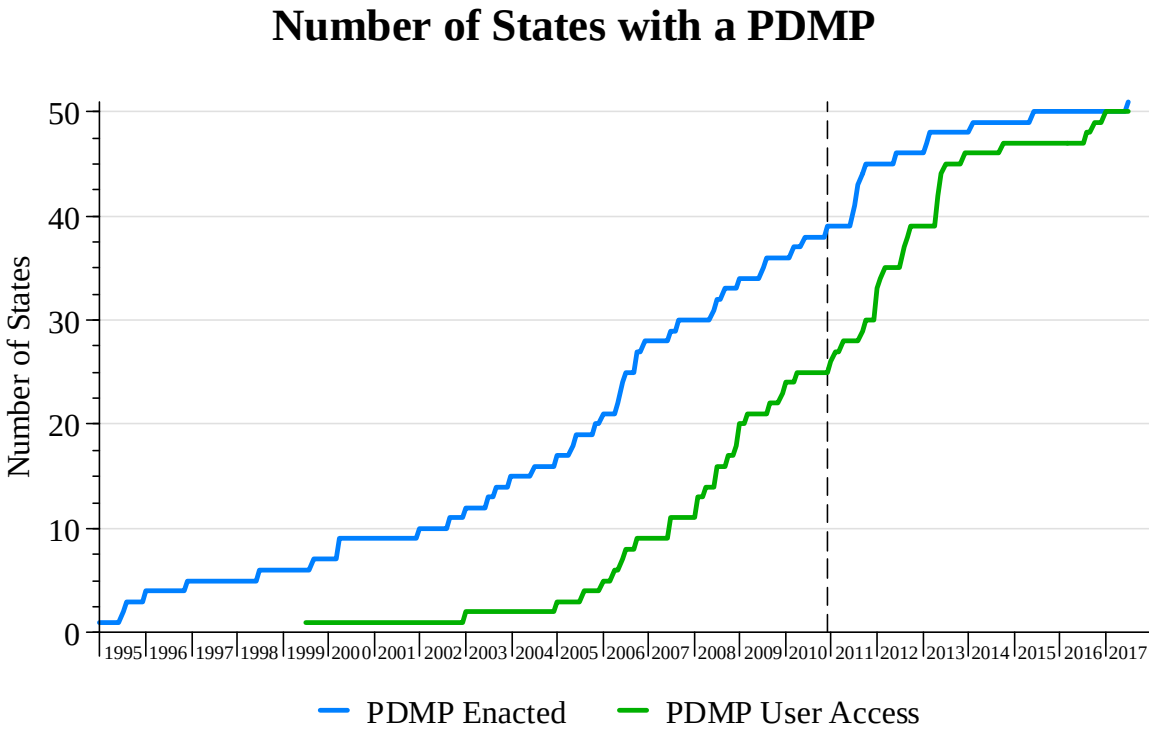
be required to form reliable economic opinions about the thickness of illicit drug markets. (*See* Cutler Deposition at 451:2-12; 361:2-17.)

141 Cutler Report Figure III.1. *See, also,* Cutler Report at ¶ 52.

was accessible to those users authorized by law to use it.[142] The exhibit shows the long time period over which states adopted PDMPs and the long time period over which PDMPs were accessible to prescribing physicians, pharmacists, and others, and no distinct jump in either trend towards the latter part of 2010. Of the 50 states plus the District of Columbia, 21 had a PDMP by 2006, 39 had one by 2011, and 50 had one by 2016. Similarly, 5 states had a PDMP that was accessible to authorized users by 2006, 26 had one by 2011, and 47 had one by 2016.

[142] Information on the dates that states enacted each PDMP and made the PDMP accessible to authorized users is from Horwitz, Jill et al., "The Problem of Data Quality in Analyses of Opioid Regulation: The Case of Prescription Drug Monitoring Programs", *NBER Working Paper Series*, August 2018 ("Horwitz et al. (2018)").

Exhibit 29



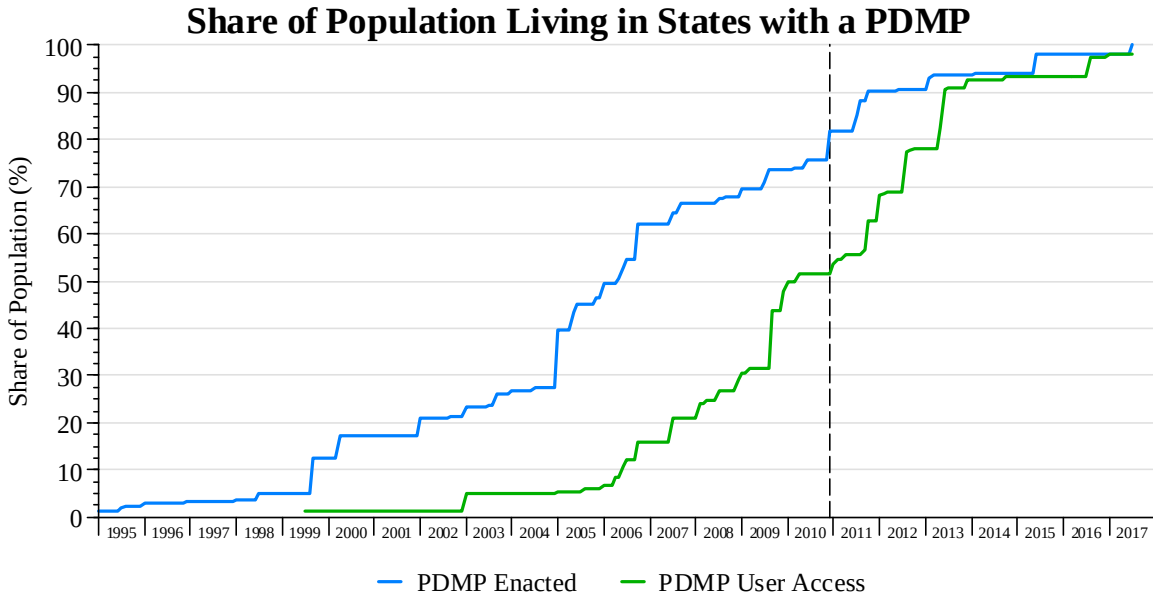
Note: PDMP Enacted represents the earliest month and year that the state had a PDMP program that was funded and had a modern,electronic PDMP (12 states had paper-based systems enacted at a prior date). PDMP User Access represents the earliest month and year that a PDMP became accessible to any user (e.g., physician, pharmacist, or member of law enforcement) authorized by state law to receive it.

Source: Horwitz et al. (2018).

158. Because the introduction of a PDMP in a highly populated state would affect more people than the introduction of a PDMP in a less populated state, I also looked at the time trends giving greater weight to more populous states. Exhibit 30 shows over time the percentage of the national population living in states with a PDMP, and the percentage living in states with a PDMP that is accessible to authorized users. The exhibit shows that percentage of the population living in areas with PDMPs grew gradually over an extended period of time and did not increase sharply in 2010. The percentage of the population living in states (or the District of Columbia) with a PDMP was 50 percent in 2006, 82 percent in

2011, and 98 percent in 2016. The percentage of the population living in states (or the District of Columbia) with a PDMP that was accessible to authorized users was 7 percent in 2006, 54 percent in 2011, and 93 percent in 2016.

Exhibit 30



Note: PDMP Enacted represents the earliest month and year that the state had a PDMP program that was funded and had a modern, electronic PDMP (12 states had paper-based systems enacted at a prior date). PDMP User Access represents the earliest month and year that a PDMP became accessible to any user (e.g., physician, pharmacist, or member of law enforcement) authorized by state law to receive it.

Sources: Horwitz et al. (2018); Census.

4. Using a direct model for illicit opioid abuse that is consistent with the theory of harm laid out in Professor Cutler's report results in much lower estimates of impact

159. Professor Cutler claims that the indirect model is "useful when the independent variable one wishes to measure is unavailable or is measured only with error."[143] Professor Cutler's theory, however, is that pre-2010 opioid shipments led to an increase in mortality

143 Cutler Report at ¶ 80.

related to illicit opioids after 2010, which means that, under his own theory, the relevant independent variable is indeed available. Professor Cutler could have examined the relationship between deaths related to illicit-opioid misuse after 2010 and pre-2010 licit-opioid shipments, but chose not to do that.

160. Under Professor Cutler's theory, mortality related to illicit-opioid misuse in the 2011-2016 period is causally determined by licit-opioid shipments from the mid-1990s through 2010. While I do not endorse Professor Cutler's direct model, I tested this theory directly by using two approaches inspired by his direct model. To account for Professor Cutler's theory that the relationship between shipments of prescription opioids and mortality shifted in 2010, I tested this theory in two ways. First, I estimated a single model in which I regressed the change in illicit-opioid mortality from 1999-2001 to 2015-2016 on cumulative average shipments from 1997-2010, and cumulative average shipments from 2011-2016 thereby allowing the relationship to change in 2010. Second, I estimated a series of models for 2011 through 2016, regressing the change in illicit-opioid mortality from 1999-2001 to each year on cumulative average shipments from 1997-2010. In other words, for 2011 I regressed the change in illicit-opioid mortality from 1999-2001 to 2010-2011 on cumulative average shipments from 1997-2010; for 2012, I regressed the change in illicit-opioid mortality from 1999-2001 to 2011-2012 on cumulative average shipments from 1997-2010; and so on, estimating one coefficient for each year of 2011 through 2016. All regressions for both methods use the same set of controls relied on by Professor Cutler in his direct model. I then applied Professor Cutler's methodology from his Table I.1 to estimate the impact of

prescription opioid shipments on illicit-opioid mortality for 2011-2016.[144] Exhibits 31 and 32 display these results. The exhibits show that the percentage-impact estimates presented in Professor Cutler's report range from about 120 to over 700 percent higher than the estimates he would have obtained had he relied on the direct approaches just described. In sum, while I do not endorse this as an appropriate method to assess causality and liability in this context, even if Professor Cutler could establish that a direct regression is reliable, and that illicit opioid misuse from 2011 to 2016 is caused by prescription opioid shipments before 2011, his indirect model would grossly overstate the impact of shipments.

[144] Note that in Exhibit 31 I do not correct for the error discussed in Section VII.B.4 where, when applying his coefficient estimate to earlier years, Professor Cutler fails to account for the fact that in earlier years fewer shipments have accumulated.

Exhibit 31

Professor Cutler's Indirect Model of Illicit Mortality Produces Inflated Impact Estimates

Comparison to a Single Direct Model with Separate Pre-2010 and Post-2010 Effects

Exhibit 32

Professor Cutler's Indirect Model of Illicit Mortality Produces Inflated Impact Estimates

Comparison to Mutliple Direct Models

D. Professors Cutler and Gruber Have Not Shown That the Defendants' Conduct Prior to 2010 Led to Increased Use of and Mortality from Illicit Opioids after 2010

1. Professor Cutler has not established that all of the changes to the illicit opioid marketplace after 2010 are outcomes of "thicker markets" or that the "thickening" is due to the Defendants' alleged misconduct

161. As motivation for using an indirect approach for estimating the impact of the alleged misconduct on illicit opioid mortality, Professor Cutler asserts that the conduct led to "thicker" markets for illicit opioids: "… the presence and sophistication of drug networks is partially a result of opioid shipments prior to 2010, as they created "thicker markets" for illegal products."[145] He reaffirms this assertion in his deposition testimony:

> *"The decrease in prices associated with heroin to a great extent are because the markets for heroin got to be what economists called thick markets, which is more people…on the supply side, more people on the demand side. The reason they got to be so thick -- the reasons the markets got to be so thick is because there were so many people that had been addicted to opioids, and then when the opioid supply was reduced they went to look for other alternatives, and heroin was a cheaper other alternative. So that led more people into the market. As a result of more people being in the market, there were more sellers, there were more buyers, and in thick markets like that prices tend to fall. I think that the reduction in heroin prices and the increase in heroin use are a result of the factors associated with the opioid – legal opioid epidemic, and they are not some exogenous change that just happened to occur."*[146]

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145 Cutler Report at ¶ 71.

146 Cutler Deposition at 321:16-322:14.

162. Professor Cutler has made no attempt to rigorously define this concept, nor does he quantify it or test this causal link in any way.[147] If it is true, however, that the conduct caused an increase in the supply of illicit opioids, I would expect that he should be able to demonstrate this in a quantifiable way. As Professor Cutler points out, there are no good data on the supply of illicit opioids. There are, however, data on seizures of illicit opioids – the same NFLIS data which Professor Cutler himself uses to estimate the share of drug crimes that are attributable to opioids. If, as Professor Cutler asserts, shipments of prescription opioids in the early 2000s led to an increase in the availability of illicit opioids post-2010, I would expect to see at least a correlation between pre-2010 shipments of prescription opioids and post-2010 seizures of illicit opioids. Using the NFLIS data on the number of times various drugs are identified in drug seizures in each state in each year, I calculate the average share of the seizures recorded in the data that are heroin or fentanyl over the period 2011-2016 for each state. In Exhibits 33 and 34, I plot these against Professor Cutler's measure of cumulative average shipments from 1997 to 2010 for each state. The exhibits show no clear relationship between pre-2010 shipments in a state and post-2010 detection of illicit opioids relative to other drugs seized.

147 Professor Cutler testified that the Alpert and Evans studies cited in his report offered evidence the markets "thickened." (See Cutler Deposition at 324:7-19; *see, also,* Cutler Report at ¶ 61.) The Alpert and Evans studies analyze the effect of the reformulation of OxyContin on heroin use, and conclude that the reformulation caused an increase in the use of heroin. These studies can be interpreted as evidence that OxyContin and heroin are substitutes. The papers do not offer evidence that the market for opioids "thickened," or that the increased availability of prescription opioids led to the increased availability of illicit opioids, including fentanyl. *See* Alpert, Abby, David Powell, and Rosalie Liccardo Pacula, "Supply-Side Drug Policy in the Presence of Substitutes: Evidence from the Introduction of Abuse-Deterrent Opioids," *American Economic Journal 10(4),* 2018, pp.1-35, at p. 3; Evans, William N., Ethan M.J. Lieber, and Patrick Power, "How the Reformulation of OxyContin Ignited the Heroin Epidemic," *The Review of Economics and Statistics 101(1),* March 2019, pp.1-15, at p. 1.

Exhibit 33

Exhibit 34

163. Also notable in these charts is the fact that, while Ohio seems to have a higher than average illicit opioid share of drug seizures, it received a level of shipments of prescription opioids roughly in line with the average across all states. This suggests that factors other than shipments of prescription opioids are driving activity in illicit opioid markets.

164. One assertion that Professor Cutler articulates clearly is his opinion that the reduction in heroin prices is a result of pre-2010 prescription opioid shipments.[148] However, other researchers have found that the declining trend in heroin prices began in the 1990s, and significant price declines had occurred well before 2010. In a 2009 study analyzing the

148 Cutler Deposition at 321:16-18.

increasing supply of heroin from South American origins and the price of heroin in 20 U.S. MSAs over the period 1993-2004, Ciccarone et al. found that as the share of heroin of South American origin increased over the sample period, the price of heroin declined significantly, declining 60 to 89 percent across the cities sampled and 62 percent on average. The authors conclude that, by 2004, these trends had led to "historically low-cost heroin in many US cities."[149]

165. Because this theory of thickening markets is not reliable and is not supported by evidence, the purported causal chain Professor Cutler describes between prescription opioid shipments and illicit opioid mortality is broken.

2. Professors Cutler has not established that prescription opioid use prior to 2010 was a "gateway" to illicit opioid use after 2010

166. In his expert report, Professor Cutler relies on establishing a link between the use of prescription opioids in the pre-2010 period and the use of illicit opioids in the post-2010 period.[150] He cites two epidemiological studies in support of this link. The first is "a survey of heroin patients in drug treatment centers that reported initiating use in the 2000s." According to Professor Cutler, this survey established that 75 percent initiated opioid use with prescription opioids whereas, among respondents that began using opioids in the 1980s, the

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149 Ciccarone, Daniel, George J. Unick, and Allison Kraus, "Impact of South American heroin on the U.S. heroin market 1993-2004," *Int J Drug Policy 20(5)*, September 2009, pp.392-401 ("Ciccarone et al. (2009)").

150 Cutler Report at ¶ 62: "Moreover, a number of epidemiological studies have established that much of the increase in the use of illicit opioids after 2010 was the result of addictions resulting from prior use of prescription opioids." However, Professor Cutler testified at deposition that he is not relying on the gateway theory: "Q. Okay. So I want to talk to you a little bit about the gateway theory. You're familiar with the gateway theory, right? A. Yes, I am familiar with it. Q. And is that something that you separately opine on in this case? A. No, I have not opined upon specifically the gateway theory." (*See* Cutler Deposition at 347:9-17.)

comparable figure was 30 percent.[151] The other is an "analysis of NSDUH survey data," which "established that among respondents that reported using both heroin and prescription opioids (for non-medical use), the share that reported initially using prescription opioids was 83 percent in 2008-10."[152]

167. The studies Professor Cutler cites do not support his conclusion that prescription-opioid use in the pre-2010 period led to heroin and fentanyl use in the post-2010 period. For the "gateway" hypothesis to be true, the probability of using heroin or fentanyl after 2010 must be higher for individuals who used prescription opioids before 2010, holding constant other factors that could lead to the use (or abuse) of both licit and illicit opioids. That is,

$$\text{Prob}(H_t|P_{t-1}, X) > \text{Prob}(H_t|{\sim}P_{t-1}, X) \qquad (1)$$

168. In this equation, H_t is heroin or fentanyl use after 2010, P_{t-1} is prescription opioid use before 2010, ${\sim}P_{t-1}$ is the absence of prescription opioid use before 2010, and X is a set of individual characteristics not caused by prescription-opioid use that could affect heroin or fentanyl use.

169. The studies Professor Cutler cites show that a large number of those who used heroin in the pre-2010 period also misused prescription opioids. That is,

$$\text{Prob}(P_{t-1}|H_{t-1})\ is\ high \qquad (2)$$

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151 Cutler Report at ¶ 62. Professor Cutler cites a 2014 study for these figures. *See*, Cicero, Theodore J., et al., "The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 Years," *JAMA Psychiatry 70(7)*, 2014, pp. 821-826 ("Cicero et al. (2014)"), at p. 823. In a more recent paper, Cicero and his co-authors note that the use of heroin as an initiating substance had increased since 2005: "the use of heroin as an initiating substance increased from 8.7% in 2005 to 31.5% in 2015." Cicero, Theodore J., Matthew S. Ellis, and Zachary A. Kasper, "Increased use of heroin as an initiating opioid of abuse: Further considerations and policy implications," *Addicted Behaviors 87*, 2018, pp. 267-271 ("Cicero et al. (2018)"), at p.267.

152 Cutler Report at ¶ 62.

170. There are at least three reasons why the statement in (2) is not informative of the inequality expressed in equation (1). The first is that, by focusing on the statement in (2), Professor Cutler is studying the wrong population. He focuses on the population that uses heroin rather than on the population that uses prescription opioids. This flaw can be seen most clearly if I replace prescription-opioid use with some other behavior, especially a behavior with high prevalence among non-heroin users. For example, the probability of drinking water conditional on using heroin or fentanyl is likely 100 percent, but this does not tell us anything about the probabilities expressed in (1). Indeed, evidence suggests that the population of prescription opioid users (the correct population to consider here) includes only a very small percentage of people who later abuse heroin.[153]

171. The second reason why Professor Cutler's approach is flawed is that he is looking at heroin use in the wrong (pre-2010) period. It is incorrect to focus on people who used heroin before 2010 in order to explain the patterns of heroin use after 2010, especially because Professor Cutler himself argues that there was a break or shift in 2010 that forced him to use a different methodological approach to analyze the post-2010 period. Moreover, mortality data show that those misusing heroin or fentanyl in the post-2010 period were

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153 Evans, William N., Ethan M.J. Lieber, and Patrick Power, "How the Reformulation of OxyContin Ignited the Heroin Epidemic," *The Review of Economics and Statistics 101(1)*, March 2019, pp.1-15, at p. 5: "According to data from the third quarter of 2010 through the end of 2014 in the annual NSDUH, among respondents who used pain medicine recreationally over the past year, less than 1 percent said they ever used heroin." Gruber Deposition at 302:6-9: "It seems very likely to me that most would not progress use to heroin use. Heroin use is a much, much lower rate than nonmedical prescription." Gruber Deposition at 395:2-10: "I don't know [what percentage of people who had a prescription opioid for a legitimate medical need and later became addicted to heroin] offhand, although studies we've looked at during today have made reference to computations like that, of that nature, which suggest that a very small minority of people who get prescriptions then transition onto heroin."

younger, on average, than the individuals misusing prescription opioids in the pre-2010 period.[154]

172. Exhibit 35 shows the national licit and illicit opioid mortality rates for people in their 20s and 30s compared with those in their 40s and 50s over time. The exhibit shows licit mortality (the blue region) peaking at around 2010 and 2011 for both age groups, and the peak licit mortality slightly higher among for those in their 40s and 50s.[155] The exhibit also shows a larger increase in overall opioid mortality driven by an increase in illicit mortality (the green region) for those in their 20s and 30s than for those in their 40s and 50s in the post-2010 time period. In other words, in the later period, the younger demographic was more affected by illicit mortality than the older demographic, while in the earlier period the older demographic was slightly more affected by licit mortality than the younger demographic. This empirical finding is not consistent with Professor Cutler's claims that post-2010 illicit-opioid mortality was driven by prescription-opioid addicts moving to illicit opioids after 2010.

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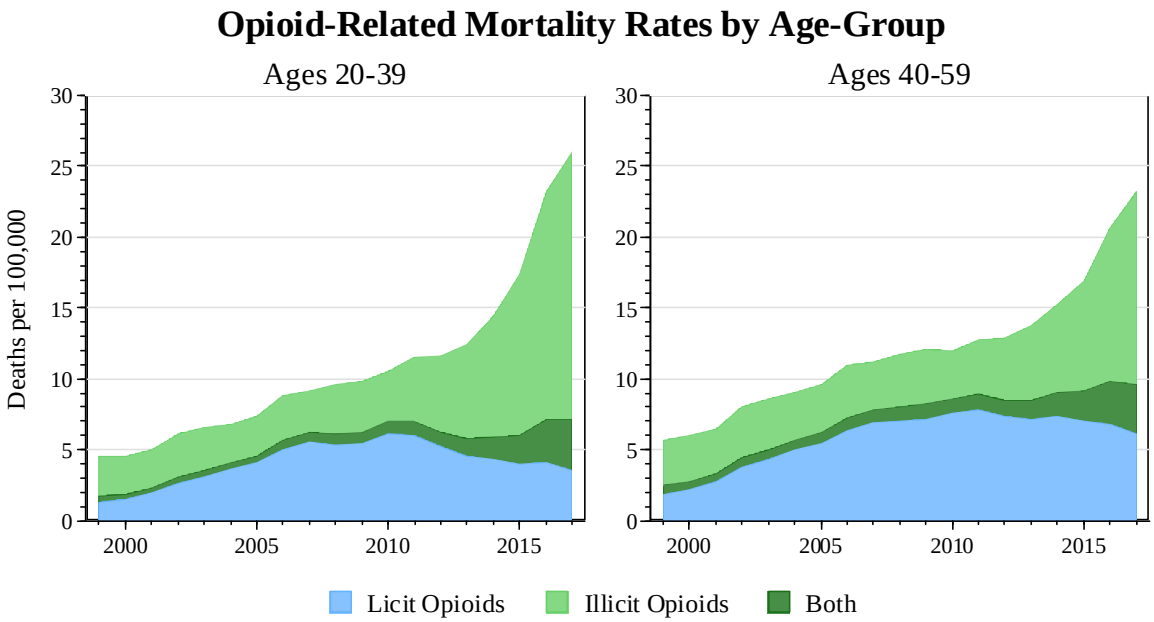
154 Ciccarone (2017) at p. 108.

155 For Exhibits 35 and 36, I rely on mortality data from CDC Wonder. I define licit mortality as mortality where drug poisoning is listed as the underlying cause of death, and a licit opioid ("methadone" or "other natural/semisynthetic opioids") is listed among the up to 20 additional "multiple" causes of death. I define illicit mortality as mortality where drug poisoning as the underlying cause of death, and an illicit opioid ("heroin," "opium," "synthetic opioids other than methadone," or "other unspecified narcotics") is listed as a multiple cause of death. A difference between this definition and the definition used by Professors Cutler and Gruber, is that Professors Cutler and Gruber classify those with both a licit opioid and an illicit opioid as a multiple cause as "illicit mortality." In Exhibit 35, I show these as "Both," and I include these deaths in both the "Licit Mortality" and "Illicit Mortality" panels in Exhibit 36.

Exhibit 35



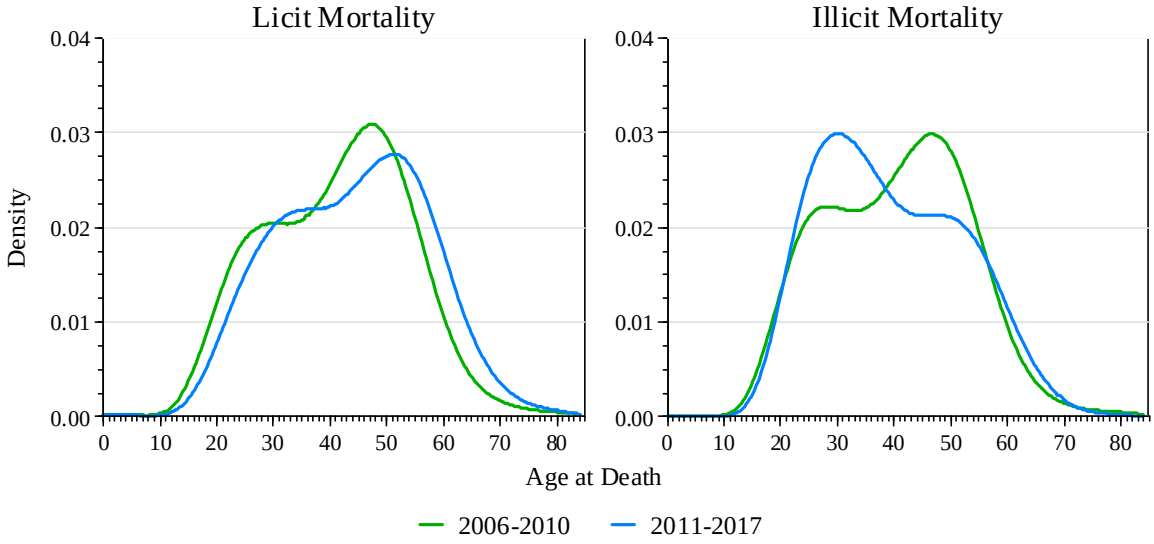
Note: Licit opioids include methadone (ICD-10 code T40.3) and other natural/semisynthetic opioids (T40.2), which includes drugs such as hydrocodone and oxycodone. Illicit opioids include heroin (T40.1), opium (T40.0), synthetic opioids other than methadone (T40.4), and other and unspecified narcotics (T40.6).

Source: CDC Wonder.

173. Exhibit 36 shows the age distribution for licit and illicit mortality for the 2006-2010 period and for the 2011-2017 period. The panel on the left shows that the age distributions for each time period were similar for licit mortality. The panel on the right shows larger differences across the two illicit mortality age distributions. When looking at illicit mortality, the distribution shifted to the left after 2010, which shows that younger workers were more affected by illicit mortality in later years.

Exhibit 36

Post-2010 Illicit Mortality Affected Younger People with Greater Intensity Than Pre-2010 Illicit Mortality or Licit Mortality in Either Period



Note: Prescription opioids include methadone (ICD-10 code T40.3) and other natural/semisynthetic opioids (T40.2), which includes drugs such as hydrocodone and oxycodone. Illicit opioids include heroin (T40.1), opium (T40.0), synthetic opioids other than methadone (T40.4), and other and unspecified narcotics (T40.6).

Source: CDC Wonder.

174. The demographic patterns in Exhibits 35 and 36 do not provide evidence that post-2010 illicit mortality was driven by prescription opioid addicts in the pre-2010 period moving to illicit opioids in the post-2010 period.

175. Finally, Professor Cutler's approach is flawed because the raw probabilities mentioned in the studies he cites disregard the personal characteristics of individuals – the *X* vector in the inequality in (1) above – that could lead people to misuse both prescription and illicit opioids.

3. The literature cited by Professor Gruber does not provide reliable evidence that those using illicit opioids would not be users of illicit opioids "but-for" the availability of prescription opioids

176. Professor Gruber cites several studies in support of his "gateway" hypothesis, all of which suffer from methodological limitations in both the survey data and epidemiological research, which make the studies not reliable for drawing broad conclusions about prescription opioids serving as a gateway to illicit opioids. One study, Jones et al. (2013) claims that, between 2002-2004 and 2008-2010, the rate of heroin use among individuals using opioid pain relievers for nonmedical purposes increased over this period and that, among those who report using both prescription opioids for nonmedical use and heroin, the share that reported using prescription opioids first increased over the same period. Professor Gruber ignores, however, the authors' caution that "the drug use estimates in this study may not generalize to the total U.S. population," which they assert is especially true for rarely used drugs like heroin.[156] Among other reasons, the authors point out that the NSDUH data used for the study are a serial cross section (rather than panel or longitudinal data), so the two cohorts in the two periods are different samples that may be influenced by different external factors. More importantly, due to the cross-sectional nature of the data, the authors state that "assessing causality is not possible."[157]

177. Professor Gruber also cites Muhuri et al. (2013) as finding an association between heroin use and prior nonmedical pain reliever (NMPR) use. This is based on NSDUH survey

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156 Jones, Christopher M., "Heroin use and heroin use risk behaviors among nonmedical users of prescription opioid pain relievers - United States, 2002-2004 and 2008-2010," *Drug and Alcohol Dependence 321*, 2013, pp. 95-100 ("Jones (2013)"), at p. 99.

157 Jones (2013) at p. 99.

data suggesting that recent heroin use was 0.39 percent among those with prior NMPR use as opposed to 0.02 percent among those without prior NMPR use. However, Professor Gruber neglects to mention that the authors also state that "*the vast majority of NMPR users have not progressed to heroin use*" (emphasis added).[158] Professor Gruber also cites the same Cicero et al. study cited by Professor Cutler, which is uninformative with regard to the risk of progressing from prescription opioid use to heroin use for the reasons I describe above.[159] Neither Professor Cutler nor Professor Gruber cite a more recent study by Cicero et al. that provides compelling evidence that heroin usage has continued to rise over recent years and may soon overtake nonmedical prescription opioids as the primary initiator of opioid use.[160]

178. Another study cited by Professor Gruber claims that use of heroin in the past month among respondents (patients in public and private treatment centers) increased after the introduction of abuse deterrent formulations (ADF);[161] however, Professor Gruber ignores other evidence that the increase in heroin use started prior to reformulation.[162]

179. Both Professors Cutler and Gruber ignore competing theories in the literature, such as the "common vulnerability" or "common liability to addiction" theory. This explanatory model presumes that there are no significant differences within the group of illicit drug users and that the selection of different drugs to consume is largely a function of

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158 Muhuri, Pradip K., Joseph C. Gfroerer, and M. Christine Davies, "Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States," *CBHSQ Data Review*, August 2013, pp. 1-15 ("Muhuri et al. (2013)"), at p. 1.

159 Cicero et al. (2014).

160 Cicero et al. (2018) at pp. 267-269.

161 Cicero, Theodore J., and Matthew S. Ellis, "Abuse-Deterrent Formulations and the Prescription Opioid Abuse Epidemic in the United States," *JAMA Psychiatry 72(5)*, 2015, pp. 424-429, at p. 428.

162 Compton, Wilson M., et al., "Relationship between Nonmedical Prescription-Opioid Use and Heroin Use," *The New England Journal of Medicine 374(2)*, 2016, pp. 154-163, especially at p. 159.

environmental factors, such as opportunity to use a given drug. These common vulnerability theories highlight that there is likely to be a strong correlation in the usage patterns in the use of different drugs, particularly those that share a similar chemical composition. For example, the same Muhuri et al. study cited by Professor Gruber states "as noted earlier, it is possible that the sequence of initiation may be driven by opportunity, and a few small-scale studies have revealed that heroin use may often precede NMPR (nonmedical pain reliever) use. For example, a qualitative study of 25 street opioid injectors in Toronto revealed that their first injection experiences were followed by transition to prescription opioids. An additional study used a retrospective chart review of 178 patients in a methadone maintenance treatment program found that 35 percent used heroin prior to initiating pain reliever use."[163]

E. Professor Cutler's Method for Estimating the Licit Mortality in 2011-2016 That He Attributes to Shipments in Approach 1 Is Inconsistent with His Theory of Substitution and Inflates His Impact Estimates

1. Professor Cutler's methodology is inconsistent with own theory

180. Professor Cutler's Table I.2 (below) shows the methodology he uses to estimate the share of post-2010 licit mortality attributable to opioid shipments in Approach 1.

163 Muhuri et al. (2013) at p. 3.

Professor Cutler's Table I.2

Percent of Licit Opioid Mortality Attributable to Shipments Based on Direct Regression Relative to Zero Shipments

181. For this calculation, Professor Cutler follows a multi-step approach. First, he uses the regression coefficient obtained from his direct model (Column C) and calculations of cumulative average shipments (Column B) to estimate the *total* opioid mortality attributable to shipments in each year from 2011 to 2016 (Column D). This estimate, which he calls the "impact on mortality," is increasing because cumulative average shipments are increasing over this period.

182. Second, Professor Cutler calculates this impact on mortality relative to the 2010 impact (Column E). The relative impact is greater than 100 percent in each year after 2010 because the estimated impact on mortality is increasing.

183. Third, he estimates the impact on *licit* mortality in 2010 using his direct model and assuming that illicit and licit mortality were affected in equal proportions that year (Column G, first row).

184. Fourth, for each year after 2010, he assumes that the increase in licit mortality relative to the 2010 impact is the same as the impact on overall mortality relative to the 2010 impact (Column G). The estimated impact on licit mortality is therefore increasing from 2011 through 2016. Because actual licit opioid mortality is decreasing throughout this period, the percent impact on licit mortality – that is, the estimated impact divided by actual mortality – is increasing.

185. Professor Cutler motivates his use of a different model after 2010 by his claims that prescription-opioid abusers switched to illicit opioids in the post-2010 period.[164] When he estimates the post-2010 licit-mortality attributable to opioid shipments, however, he does not take this alleged substitution into account. An outcome of his methodology is, rather, that the licit mortality attributable to shipments increases substantially from 2011 through 2016.

186. Exhibit 37 shows graphically Professor Cutler's estimates of the licit and illicit mortality attributable to shipments.[165] The charts show the actual licit and illicit mortality from 2006 through 2016, as well as Professor Cutler's estimates of the licit and illicit mortality attributable to shipments. As shown in the exhibit, Professor Cutler's estimates of both the attributable *licit* mortality and the attributable illicit mortality increased after 2010.

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164 Cutler Report at ¶¶ 48-51.

165 Professor Cutler does not provide separate estimates for the impact on licit vs. illicit opioid mortality for the years prior to 2010. However, he assumes that they were each affected proportionately. I apply this same assumption to years 2006 through 2009 in Exhibit 37.

Exhibit 37

Actual Opioid Mortality and Professor Cutler's Estimates

187. Exhibit 37 shows the fundamental inconsistency at the heart of Professor Cutler's theory. Professor Cutler argues that, because licit-opioid shipments declined after 2010, users switched to illicit opioids and, as a consequence, illicit opioid mortality increased dramatically.[166] Professor Cutler claims that the post-2010 illicit opioid mortality attributable to shipments went up dramatically in 2010 because people were substituting from licit to illicit opioids.[167] But he does not take into account this substitution when estimating the number of licit deaths attributable to shipments – his estimates of licit mortality attributable to

166 *See* Cutler Report at ¶¶ 45-55.

167 Cutler Deposition at 546:20-24: "Q. And this is happening at a period where, according to your theory, folks who are addicted to prescription opioids were substituting into illegal opioids, right? A. Yes, that is correct."

shipments are increasing during the 2011-2016 period. Professor Cutler testified that he had no evidence to support his conclusion that licit mortality attributable to shipments would increase after 2010.[168]

188. Exhibit 38 shows Professor Cutler's estimates of the *share* of licit and illicit mortality attributable to shipments from 2006 through 2016. The exhibit shows a dramatic increase in the share of both licit and illicit mortality attributable to shipments after 2010.

Exhibit 38

The Share of Opioid Mortality That Professor Cutler Attributes to Shipments

[168] Cutler Deposition at 547:1-548:3.

189. Professor Cutler's assumption that the impact on licit mortality would increase dramatically after 2010 is inconsistent with his claims that a variety of factors designed to curtail the abuse of prescription opioids led to fewer shipments of prescription opioids after 2010 – and, presumably, fewer shipments of those prescriptions most likely to be diverted to misuse and abuse.[169] If, according to Professor Cutler, prescription opioids were becoming more difficult to obtain and abuse, the share of licit mortality attributable to shipments should be declining, not increasing, and not increasing at the dramatic rate that Professor Cutler assumes they would increase.

190. In short, the application of Professor Cutler's theory to the post-2010 period reveals the theory's fundamental flaws and inconsistencies. For one, Professor Cutler's theory relies on the contradictory assumption that an increase in opioid shipments before 2010 led to an increase in illicit-opioid mortality, but a decrease in shipments after 2010 also led to an increase in illicit-opioid mortality. Put differently, no matter whether shipments increased or decreased, in Professor Cutler's view they always led to more illicit-opioid mortality. In addition, Professor Cutler argues that opioid shipments accounted for an increasing share of licit-opioid mortality attributable to shipments after 2010 despite the fact that, as he acknowledges, shipments declined considerably after 2010.

2. Professor Cutler's methodology can estimate licit mortality attributable to shipments that is greater than actual licit mortality

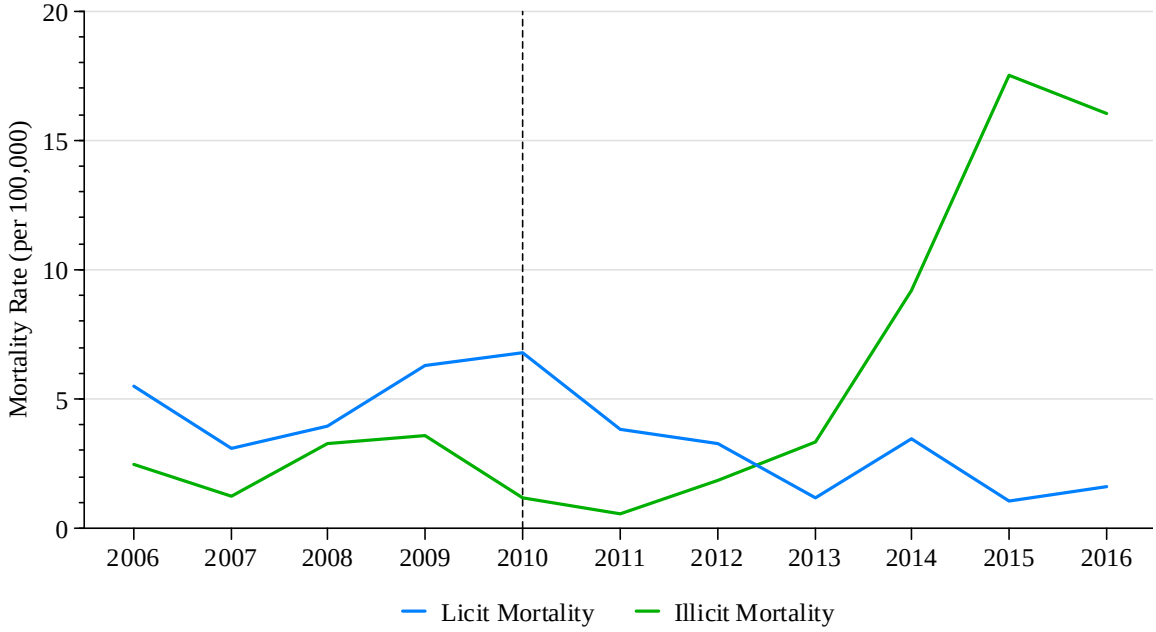
191. The flaws in Professor Cutler's methodology for estimating the share of mortality attributable to shipments after 2010 can be seen readily in a sample county that would seem to

169 Cutler Report at ¶ 52.

fit his theory that users of prescription opioids substituted to illicit opioids after 2010. One such county is Wood County, Ohio. Wood County, Ohio is among the 400 counties included in Professor Cutler's regression model. Exhibit 39 shows that Wood County had a large increase in illicit mortality after 2010 and a decline in licit mortality around that same time. Without careful analysis, this pattern appears to be consistent with Professor Cutler's theory that abusers of opioids substituted from licit to illicit opioids after 2010.

Exhibit 39

Opioid Mortality Rates in Wood County, Ohio



Sources: ARCOS, NVSS, Census data from Plaintiffs' expert's backup materials.

192. Exhibit 40 shows the prescription opioid shipments to Wood County from 1997 to 2016. [redacted], which is also consistent with Professor Cutler's theory that the reduction in prescription opioid shipments caused people to substitute from licit to illicit opioids after 2010.

Exhibit 40

Opioid Shipments per Capita

Wood County, Ohio

193. Exhibit 41 shows the actual licit mortality, and the licit mortality attributable to shipments resulting from the application of Professor Cutler's methodology to the shipments and mortality figures from Wood County.[170] As shown in the chart, the licit mortality attributable to shipments *exceeds* the actual licit mortality for years 2011-2016. In 2016, for example, the actual licit opioid mortality rate in Wood County was 1.6 per 100,000. Applying Professor Cutler's methodology, however, implies that there were [redacted] deaths per 100,000 attributable to shipments, which implies a percentage impact of more than 100 percent.

170 The calculations used to create Exhibit 41 are shown in Exhibit C-20 in Appendix C.

Exhibit 41

Applying Professor Cutler's Methodology to Wood County Produces Nonsensical Results

194. Implausible results such as these show that Professor Cutler's methodology for estimating "impact" is unreliable.

F. Professor Cutler's Crime Regression Does Not Establish that Shipments Led to Increased Criminal Activity

195. In an attempt to corroborate his method of using mortality as a proxy for other harms, Professor Cutler proffers two direct regressions of property and violent crimes on prescription opioid shipments. His regression analysis results in a positive correlation and, like with his mortality regressions, Professor Cutler interprets this causally, ignoring the possible explanation that places with more crime might also be places with higher demand for drugs. As such, as with Professor Cutler's direct mortality regression, his crime regression

also suffers from omitted variable bias. As I discuss above in Section VI. C, Professor Cutler's direct model does not account for underlying despair conditions reflected, in part, by the non-opioid deaths of despair measures I use above to demonstrate the omitted variable bias in his direct regression approach. The same can proxies for despair can be used to demonstrate the omitted variable bias in his crime regressions. I ran a version of Professor Cutler's two crime regression and added these measures of non-opioid "deaths of despair" as an additional control variable. The data I use for the deaths of despair measures are not available for all of the counties included in Professor Cutler's crime regressions, so I also ran a version of his baseline regressions restricted to the counties for which the deaths of despair measure are available and include these results as well.[171] For the models in Exhibits 42 and 43, the changes in the crime rates, the despair proxies, and the economic and demographic control variables, are measured from 1999-2001 to 2015-2016, because the earliest year for which I have consistent data on the "deaths of despair" measures is 1999.

196. Exhibits 42 and 43 below displays the coefficients on shipments obtained from my modified crime regressions, and Professor Cutler's baseline regressions restricted to the same sample. As shown in the exhibits, including the non-opioid deaths of despair as controls in the model reduces the coefficients on shipments. When I calculate the non-opioid deaths of despair using Method 1, it reduces the coefficients in the property crime and violent crime regressions by 46 and 15 percent, respectively. When I calculate the non-opioid deaths of despair using Method 2, it reduces the coefficient in the property crime regression by 38 percent and the coefficient in the violent crime regression by 12 percent. To the extent that

171 The full results of regressions are included in Exhibits C-21 through C-28 of Appendix C.

there are other omitted variables that are correlated both with shipments and crime, these are lower bounds on the degree to which Professor Cutler overestimates the alleged impact.

Exhibit 42

Controlling for Proxies for Despair Conditions Reduces Professor Cutler's Estimates of Impact on Property Crime

Exhibit 43

Controlling for Proxies for Despair Conditions Reduces Professor Cutler's Estimates of Impact on Violent Crime

VIII. ESTIMATING THE SHARE OF ALLLEGED HARMS ATTRIBUTABLE TO OPIOIDS

A. The Use of Mortality as a Proxy for Harms

197. Professor Cutler uses opioid-related mortality as a proxy for other harms.[172] There are many reasons to doubt the appropriateness of mortality as a proxy for other harms, and Professor Cutler does establish a relationship between mortality these various outcomes. In particular, Professor Cutler assumes, rather than demonstrates, that opioid-related mortality is a good proxy for the following harms (to the extent that he has determined they are opioid-related): crime, juvenile court activity, addiction and mental health activity, and children and family services.

198. The harms alleged in the Plaintiffs' complaints do not lend themselves to such a uniform characterization. To begin, as discussed above, Professor Cutler counts as opioid-related crimes those that are committed under the influence of opioids and those that are committed for opioid-related reasons (i.e., those that are committed to acquire money to purchase opioids, and trafficking of opioids); there is no reason to believe that these crimes would be proportional to opioid-related mortality. Opioid-related juvenile court activity is determined similarly – namely as the share of juvenile crimes that are opioid-related, and the share of "Abuse, Dependency, Neglect" cases that are opioid-related child removals. Similarly, Professor Cutler uses the share of children taken into custody that had parents who were using opioids at the time of removal. Unless these child removals are due to an opioid-related death of a parent, it is not clear that they should be proportional to opioid-related

[172] Cutler Report at ¶ 47.

mortality. Finally, for the share of addiction and mental health services that are opioid-related, Professor Cutler uses the share of board expenditures that are associated with addiction services, and the share of individuals receiving addiction services for opioids (for Cuyahoga) or the share of addiction expenditures used for Opioid Use Disorder (for Summit).

199. Summit and Cuyahoga County allege that these harms are related to opioid use or abuse, not opioid-related mortality, and Professor Cutler does not establish a relationship between prescription opioid shipments and these alleged harms – he simply assumes that if a given percent of opioid-related deaths are attributable to prescription opioid shipments, then the same percent of the above harms are also attributable to prescription opioid shipments.

200. Contrary to Professor Cutler's assumption, mortality is not a reliable proxy for opioid-related harm. One reason that the relationship may not hold is the greater danger posed by illicit opioids like heroin and fentanyl. Mortality is a function of the supply and purity of these drugs, both of which increased over the relevant period. A study by Ciccarone et al. found that over the period 1993-2004, the share of heroin coming from South America increased significantly and this increase was a significant predictor of both higher purity and lower prices.[173] Increased purity alone could cause an increase in mortality, even without an increase in use or abuse. As Cicero et al. note in a recent study:

> *Given that opioid novices have limited tolerance, the risk of fatal overdose for heroin initiates is elevated compared to prescription opioids, particularly given non-oral administration and often unknown purity/adulterants (i.e., fentanyl). Imprecision of titrating dose among opioid novices may explain observed increases opioid overdoses.*[174]

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173 Ciccarone et al. (2009).

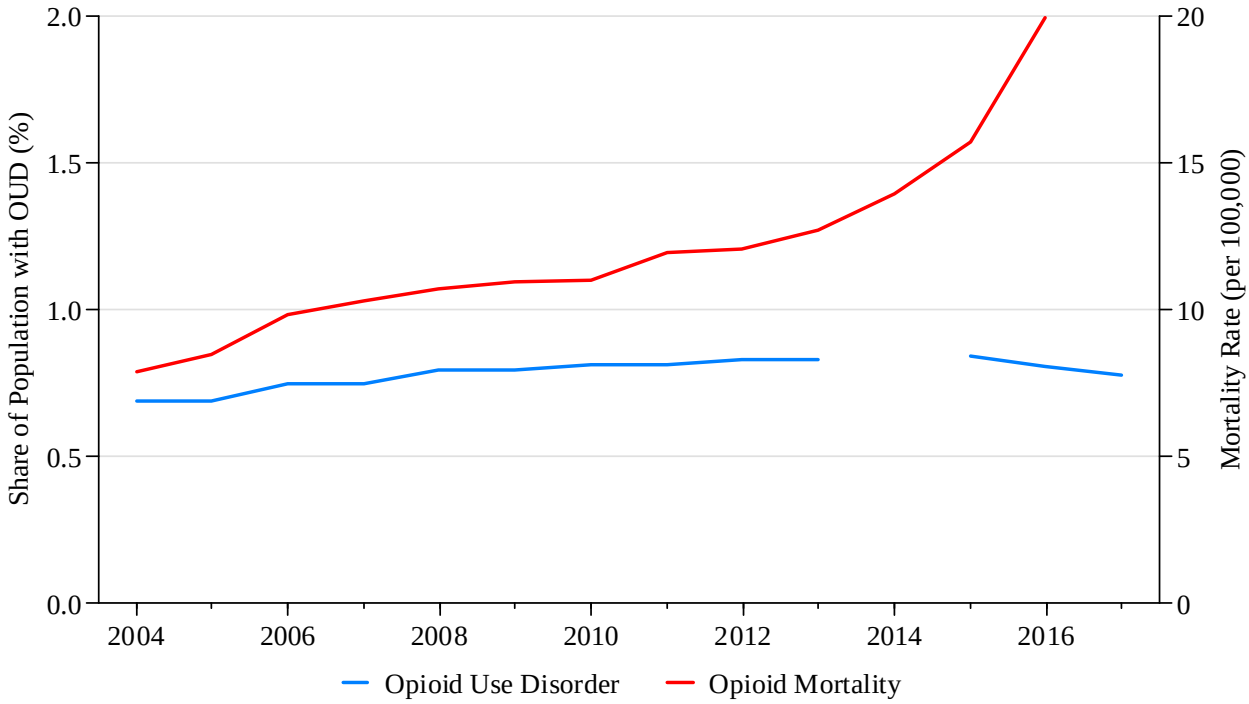
174 Cicero et al. (2018) at p. 267.

201. In fact, Professor Cutler himself has reviewed evidence that the trend in Opioid Use Disorder (OUD) is different from the trend in opioid-related mortality. In estimating the share of some of the drug-related crimes he studies, he uses data from the National Survey on Drug Use and Health (NSDUH) on the share of individuals with Substance Use Disorders (SUD) who have OUD. I use the same data and plot the national trend in OUD along with the national trend in opioid-related mortality. (*See* Exhibit 44.) The two trends do not follow the same pattern, with the trend in mortality increasing more rapidly than the trend in OUD, and the trend in OUD flattening out (or even declining) during the period over which the trend in mortality is increasing most rapidly.[175]

[175] Data for 2014 are not reported, and the definition of OUD changed in that year, so some of the decline may be due to this change; in his own analysis, Professor Cutler assumes that the trend is flat from 2013 onward, the same period over which opioid-related mortality is increasing most rapidly.

Exhibit 44

The National Trend in OUD Does Not Closely Track Opioid Mortality



Sources: NVSS data from Plaintiffs' experts' backup materials; NSDUH.

B. Criminal Activity

202. Additional problems make Professor Cutler's estimates of the share of criminal activity attributable to opioid shipments unreliable.

1. Professor Cutler ignores crime that occurs even in the absence of the allegedly excessive opioid shipments

203. Professor Cutler claims that the percentage of criminal activity that is opioid related ranges from 5.4 to 12.2 percent, depending on type of criminal activity and year. It is incorrect to claim, as he seems to do, that, in the absence of the allegedly excessive opioid shipments, criminal activity would have declined between 5.4 and 12.2 percent. In the

absence of opioid shipments, some people who committed crimes related to opioids would likely have committed other crimes unrelated to opioids.

204. At a minimum, Professor Cutler should consider some baseline rate of criminal activity that would have likely prevailed among those who were convicted of opioid-related crimes (in the absence of the allegedly excessive opioid shipments). Since the characteristics of criminals differ from those of non-criminals, Professor Cutler should take these differences into account when considering the baseline level of criminal activity that would have prevailed in the "but-for" world. Specifically, Professor Cutler should also take into account that many drug dealers would have sold other narcotics in the absence of the allegedly excessive opioid shipments.

205. Finally, Professor Cutler argues that illicit opioids and prescription opioids are substitutes, but disregards the fact that, if this is indeed so, crimes driven by illicit opioids would have increased in a world with no (or lower) availability of prescription opioids.

2. Drug crimes

206. To estimate the share of criminal activity attributable to opioids, Professor Cutler first estimates the share of criminal activity that is "directly or indirectly motivated by drugs."[176] He then assumes that the share of drug crimes that is opioid-related is proportional to the share of drug seizures in which an opioid was detected (for crimes reported as "drug crimes") or to the share of individuals with SUD in Ohio that have OUD (for other crimes that are identified as drug-related).[177]

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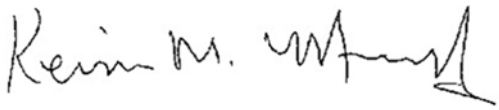
176 Cutler Report at ¶ 38.

177 Cutler Report at ¶ 39.

207. Professor Cutler states that "[d]rug crimes are defined to include those involving the purchase or sale of illicit drugs as well as estimates of the share of other crimes undertaken to obtain drugs or to obtain money to purchase drugs."[178] I note first that, by definition, these crimes do not involve prescription (licit) opioids. In addition, the amount of criminal activity associated with a particular type of drug need not be proportional to the number of seizures containing that drug, or to the share of people with SUDs that have OUD. Moreover, the data on drug seizures count the number of times a particular drug was detected in a seizure. The data do not provide information on the weight of the drugs seized or the share of the seizure that involved an opioid (as opposed to another illicit drug).



Kevin M. Murphy, Ph.D.

June 21, 2019

178 Cutler Report at ¶ 38.

Appendix A: Curriculum Vitae

Curriculum Vitae

Kevin M. Murphy

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Current Positions

July 2005-Present: George J. Stigler Distinguished Service Professor of Economics, Department of Economics and Booth School of Business, The University of Chicago

Faculty Research Associate, National Bureau of Economic Research

Co-Director, Health and Human Capital Program, Health Economics Initiative, Becker Friedman Institute

Education

University of California, Los Angeles, A.B., Economics, 1981

The University of Chicago, Ph.D., 1986

Thesis Topic: *Specialization and Human Capital*

Previous Research and Academic Positions

2002-2005: George J. Stigler Professor of Economics, Department of Economics and Booth School of Business, The University of Chicago

1993 – 2002: George Pratt Shultz Professor of Business Economics and Industrial Relations, The University of Chicago

1989 – 1993: Professor of Business Economics and Industrial Relations, The University of Chicago

1988 – 1989: Associate Professor of Business Economics and Industrial Relations, The University of Chicago

1986 – 1988: Assistant Professor of Business Economics and Industrial Relations, The University of Chicago

1983 – 1986: Lecturer, Booth School of Business, The University of Chicago

1982 – 1983: Teaching Associate, Department of Economics, The University of Chicago

1979 – 1981: Research Assistant, Unicon Research Corporation, Santa Monica, California

Honors and Awards

2008: John von Neumann Lecture Award, Rajk College, Corvinus University, Budapest

2007: Kenneth J. Arrow Award (with Robert H. Topel)

October 2005: Garfield Research Prize (with Robert H. Topel)

September 2005: MacArthur Foundation Fellow

1998: Elected to the American Academy of Arts & Sciences

1997: John Bates Clark Medalist

1993: Fellow of The Econometric Society

1989 – 1991: Sloan Foundation Fellowship, The University of Chicago

1983 – 1984: Earhart Foundation Fellowship, The University of Chicago

1981 – 1983: Fellowship, Friedman Fund, The University of Chicago

1980 – 1981: Phi Beta Kappa, University of California, Los Angeles

1980 – 1981: Earhart Foundation Fellowship, University of California, Los Angeles

1979 – 1981: Department Scholar, Department of Economics, University of California, Los Angeles

Publications

Books

Social Economics: Market Behavior in a Social Environment with Gary S. Becker, Cambridge, MA: Harvard University Press (2000).

Measuring the Gains from Medical Research: An Economic Approach, edited volume with Robert H. Topel, Chicago: The University of Chicago Press (2003).

Chapters in Books

"Income and Wealth in America," with Emmanuel Saez, in Inequality and Economic Policy, ed. Tom Church, Christopher Miller, John B. Taylor, Stanford, CA: Hoover Press (2015)

Articles

"Government Regulation of Cigarette Health Information," with Benjamin Klein and Lynne Schneider, 24 *Journal of Law and Economics* 575 (1981).

"Estimation and Inference in Two-Step Econometric Models," with Robert H. Topel, 3 *Journal of Business and Economic Statistics* 370 (1985).

"Unemployment, Risk, and Earnings: Testing for Equalizing Wage Differences in the Labor Market," with Robert H. Topel, in Unemployment and the Structure of Labor Markets, pp. 103-139, ed. Kevin Lang and Jonathan S. Leonard. London: Basil Blackwell (1987).

"The Evolution of Unemployment in the United States: 1968-1985," with Robert H. Topel, in NBER Macroeconomics Annual, pp. 11-58, ed. Stanley Fischer. Cambridge, MA: MIT Press (1987).

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"The Family and the State," with Gary S. Becker, 31 *Journal of Law and Economics* 1 (1988).

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"Income Distribution, Market Size, and Industrialization," with Andrei Shleifer and Robert W. Vishny, 104 *Quarterly Journal of Economics* 537 (1989).

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"Empirical Age-Earnings Profiles," with Finis Welch, 8 *Journal of Labor Economics* 202 (1990).

"Human Capital, Fertility, and Economic Growth," with Gary S. Becker and Robert F. Tamura, 98 *Journal of Political Economy*, S12 (1990).

"Accounting for the Slowdown in Black-White Wage Convergence," with Chinhui Juhn and Brooks Pierce, in Workers and Their Wages: Changing Patterns in the United States, pp. 107-143, ed. Marvin Kosters. Washington, D.C.: American Enterprise Institute (1991).

"The Role of International Trade in Wage Differentials," with Finis Welch, in Workers and Their Wages: Changing Patterns in the United States, pp. 39- 69, ed. Marvin Kosters. Washington, D.C.: American Enterprise Institute (1991).

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Appendix B: List of Materials Relied Upon

List of Materials Relied Upon

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Data

ARCOS Data

IQVIA Data

NVSS Data

Appendix C: Exhibits

Exhibit C-1

Regression Results: Non-Opioid Deaths of Despair Method 1

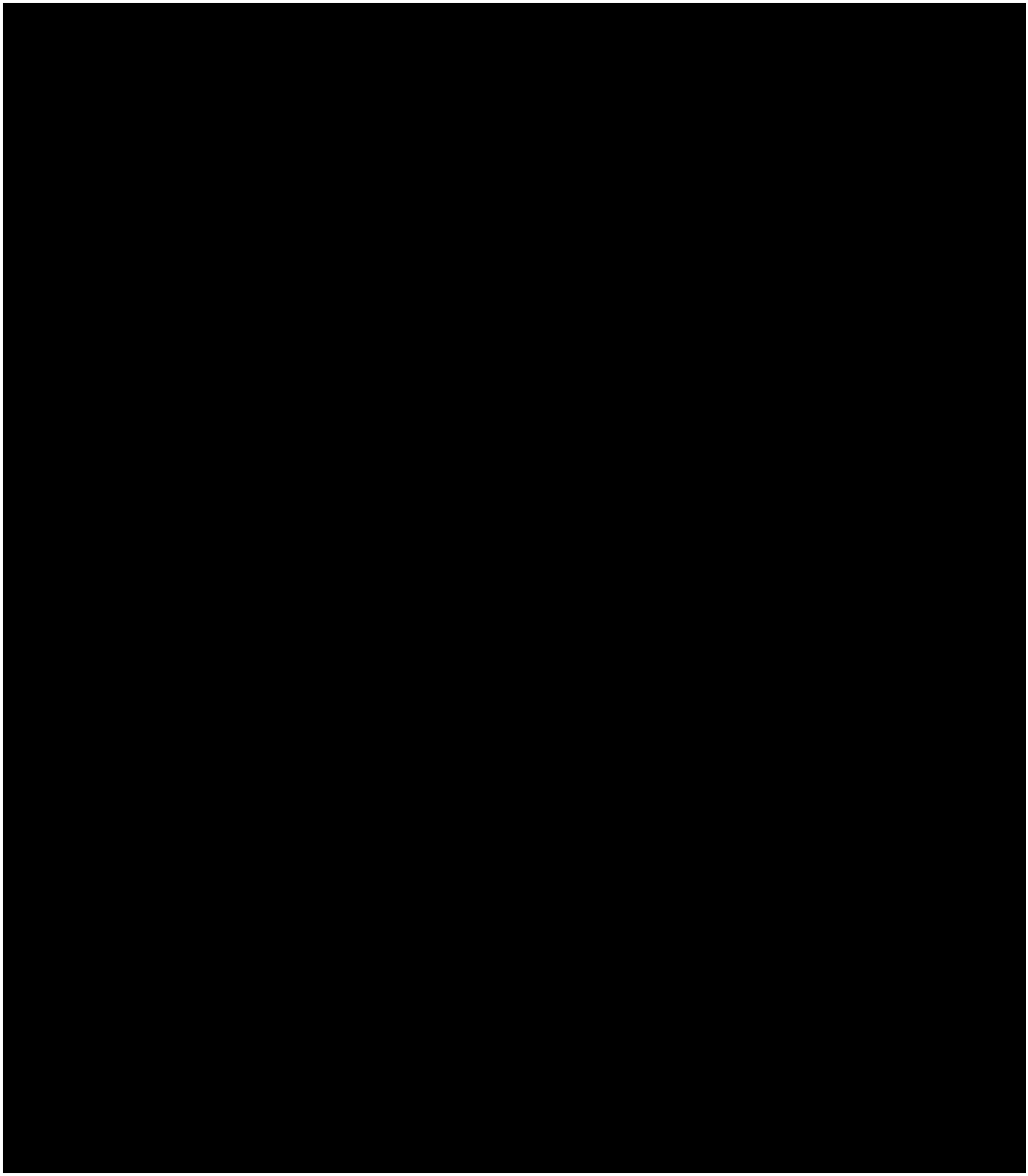

Exhibit C-2

Regression Results: Non-Opioid Deaths of Despair Method 2

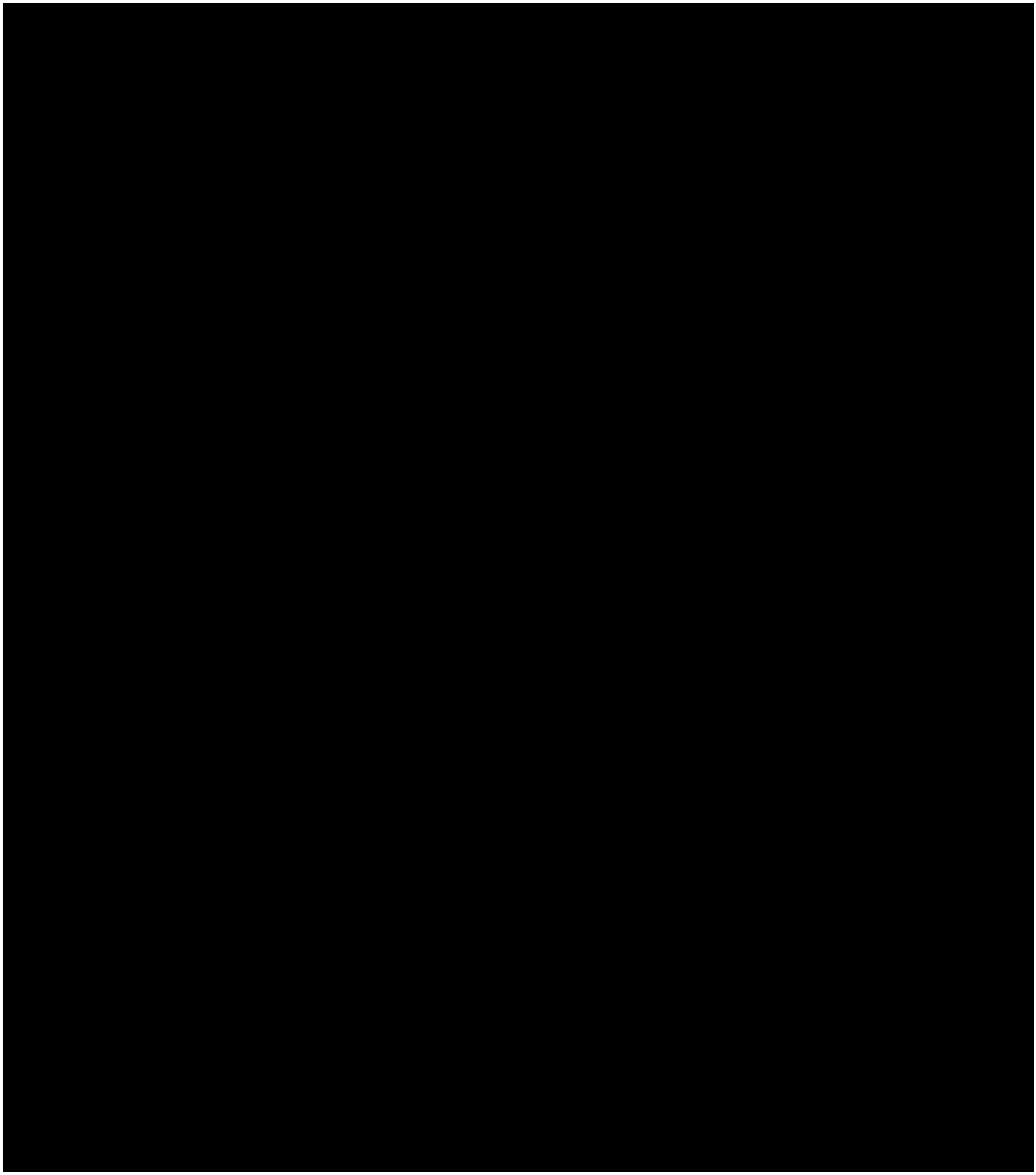

Exhibit C-3

Direct Model for Cancer Mortality Rate from 1993-1995 to 2009-2010

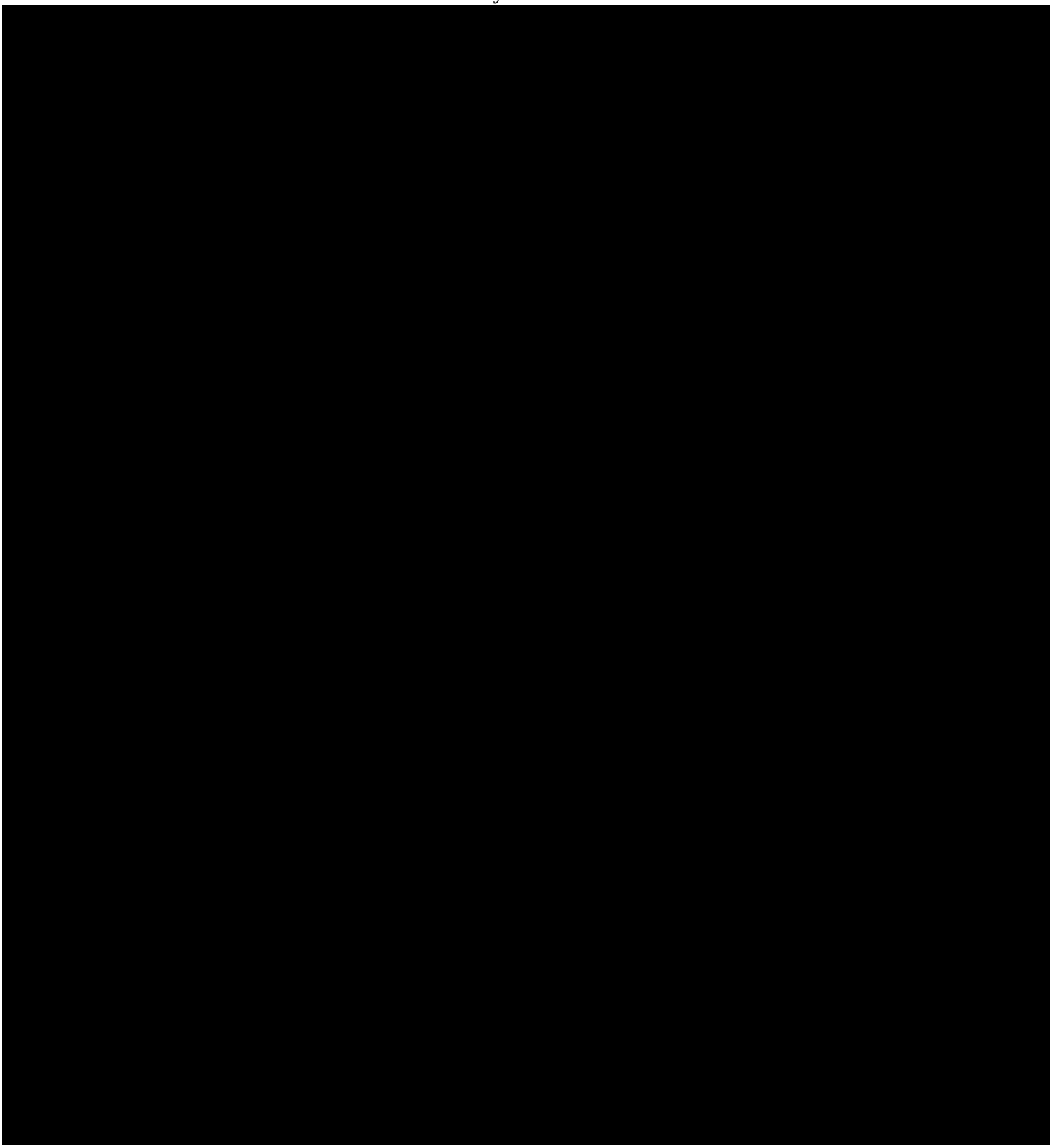

Exhibit C-4

Direct Model for Opioid Mortality Rate from 1993-1995 to 2009-2010

Large Counties

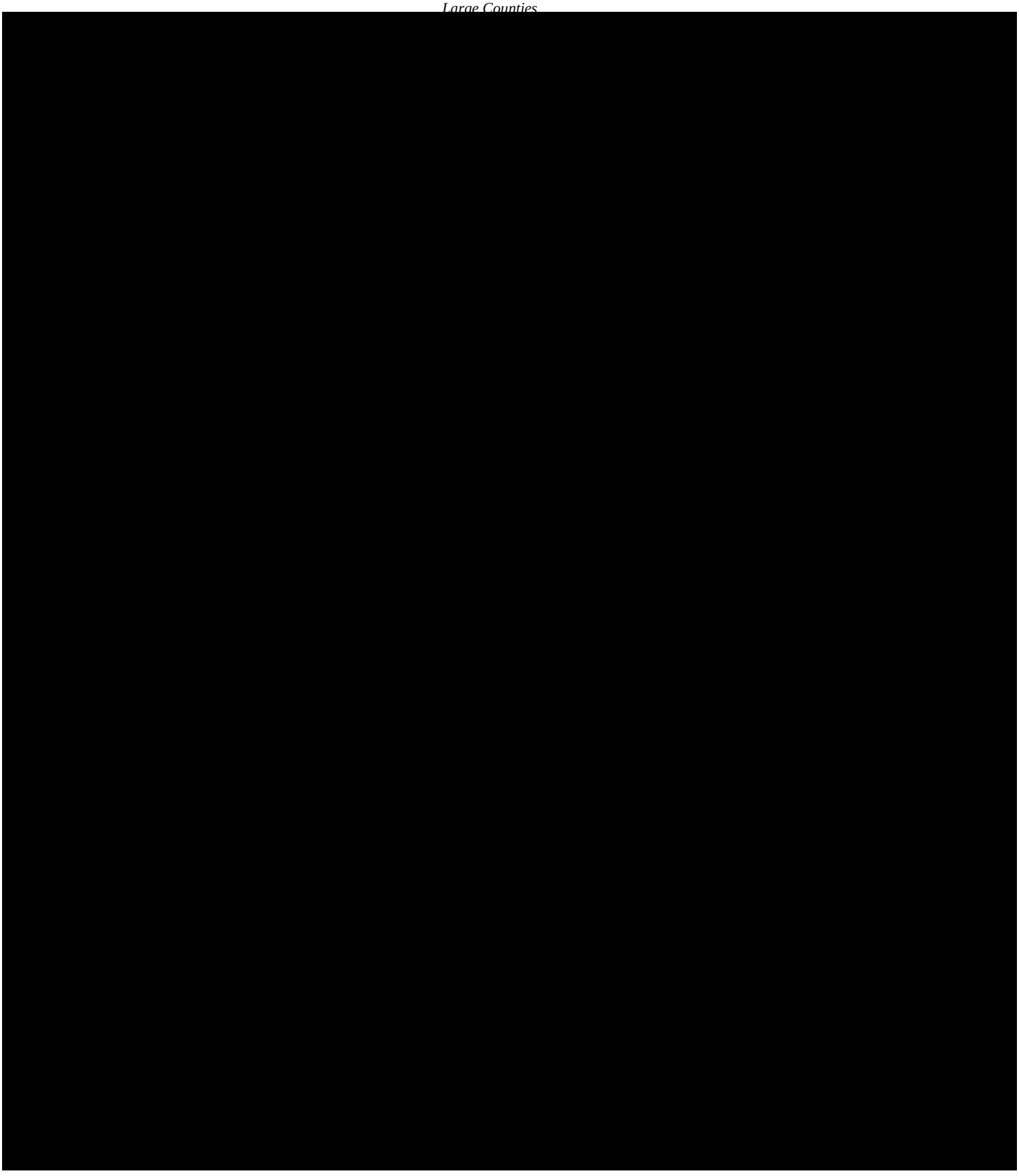

Exhibit C-5

Many Low-Shipment Counties Have Above-Average Licit Opioid Mortality

Year	National Average Licit Opioid Mortality	Share of Counties in **Bottom**-Shipment Quartile with Licit Mortality Rates **Above** the National Average		Share of Counties in **Top**-Shipment Quartile with Licit Mortality Rates **Below** the National Average	
		Share of Counties	Share of Population	Share of Counties	Share of Population
1999	2.7	16%	35%	56%	50%
2000	3.0	15%	29%	40%	31%
2001	3.4	13%	22%	35%	29%
2002	4.4	19%	29%	45%	34%
2003	4.9	12%	17%	32%	26%
2004	5.3	16%	16%	29%	21%
2005	5.7	21%	20%	29%	21%
2006	6.5	16%	13%	30%	25%
2007	7.1	12%	8%	27%	22%
2008	7.1	13%	10%	27%	20%
2009	7.0	22%	13%	28%	20%
2010	7.2	13%	10%	20%	17%
2011	7.5	18%	11%	21%	16%
2012	6.8	19%	6%	31%	27%
2013	6.2	18%	10%	24%	18%
2014	5.7	16%	9%	21%	22%
2015	5.3	26%	13%	21%	20%
2016	5.1	21%	13%	23%	26%

Source: Backup materials to the expert report of Professor Gruber.

Exhibit C-6

Many Low-Shipment Counties Have Above-Average Illicit Opioid Mortality and Many High-Shipment Counties Have Below-Average Illicit Opioid Mortality

Year	National Average Illicit Opioid Mortality	Share of Counties in **Bottom**-Shipment Quartile with Illicit Mortality Rates **Above** the National Average		Share of Counties in **Top**-Shipment Quartile with Illicit Mortality Rates **Below** the National Average	
		Share of Counties	Share of Population	Share of Counties	Share of Population
1999	2.9	16%	49%	62%	52%
2000	2.7	21%	48%	60%	52%
2001	2.6	18%	51%	50%	38%
2002	2.9	19%	46%	49%	43%
2003	2.8	18%	41%	42%	37%
2004	2.6	19%	33%	44%	37%
2005	2.7	28%	20%	47%	32%
2006	3.3	13%	23%	46%	37%
2007	3.0	18%	16%	41%	34%
2008	3.5	18%	14%	44%	43%
2009	3.8	29%	17%	38%	31%
2010	3.6	25%	16%	43%	38%
2011	4.3	34%	21%	44%	38%
2012	5.1	29%	19%	49%	44%
2013	6.5	21%	21%	45%	42%
2014	8.2	18%	16%	49%	50%
2015	10.4	22%	19%	48%	48%
2016	14.7	24%	20%	47%	46%

Source: Backup materials to the expert report of Professor Gruber.

Exhibit C-7

Regression Results: Controlling for Non-Opioid Deaths of Despair Method 1

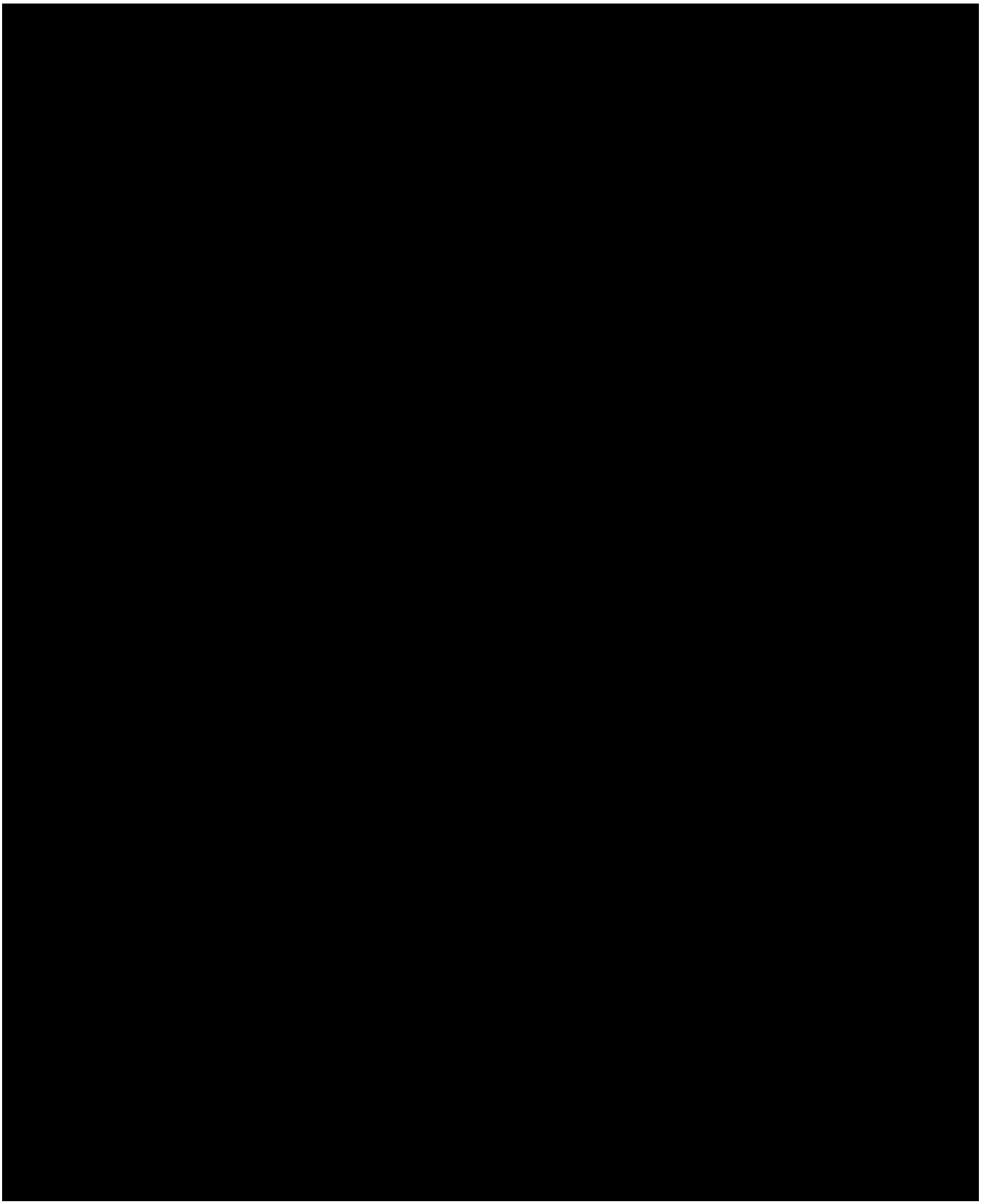

Exhibit C-8

Regression Results: Controlling for Non-Opioid Deaths of Despair Method 2

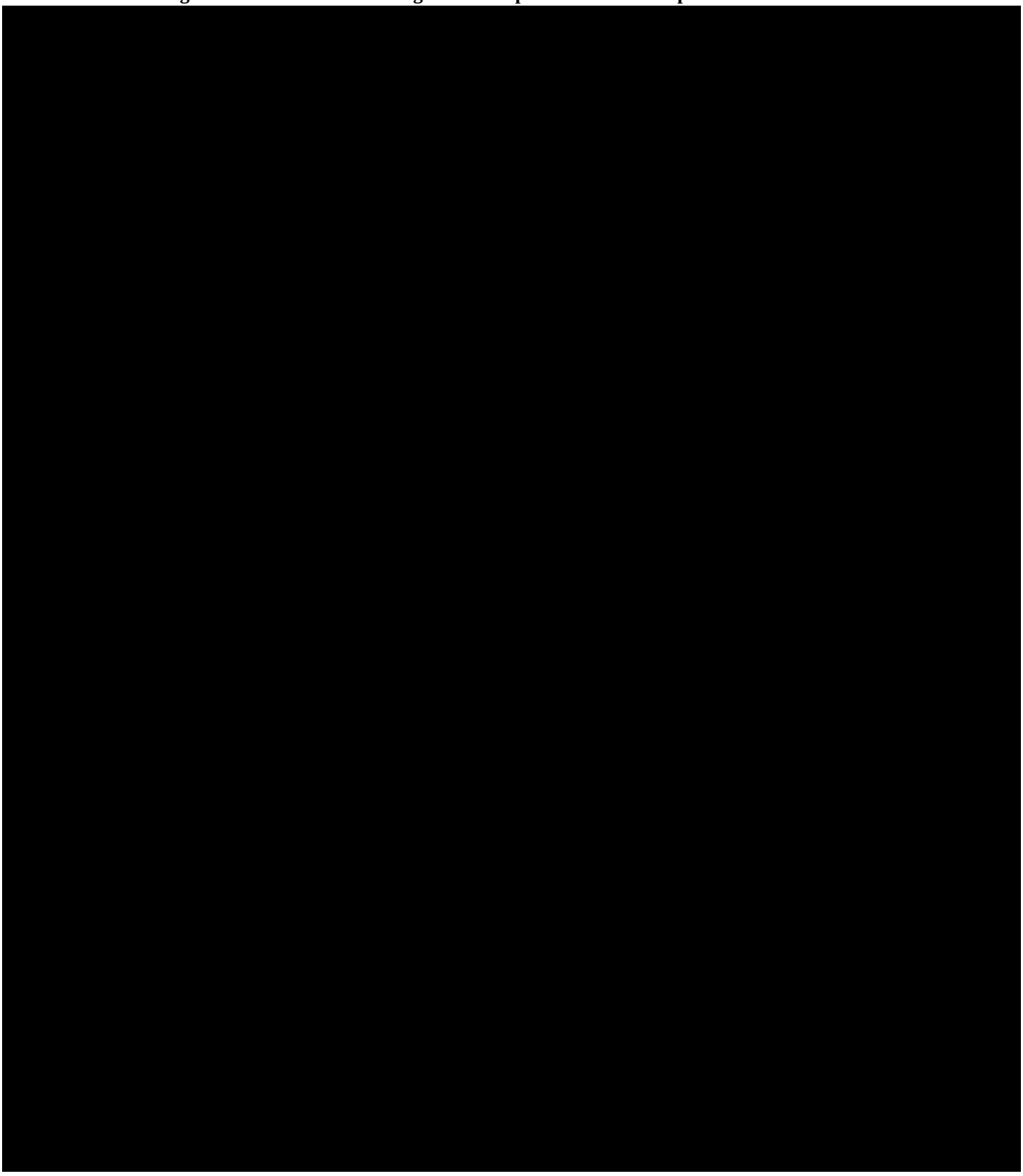

Exhibit C-9

Regression Results: Professor Cutler's Direct Model, 1999-2001 to 2009-2010

Large Counties

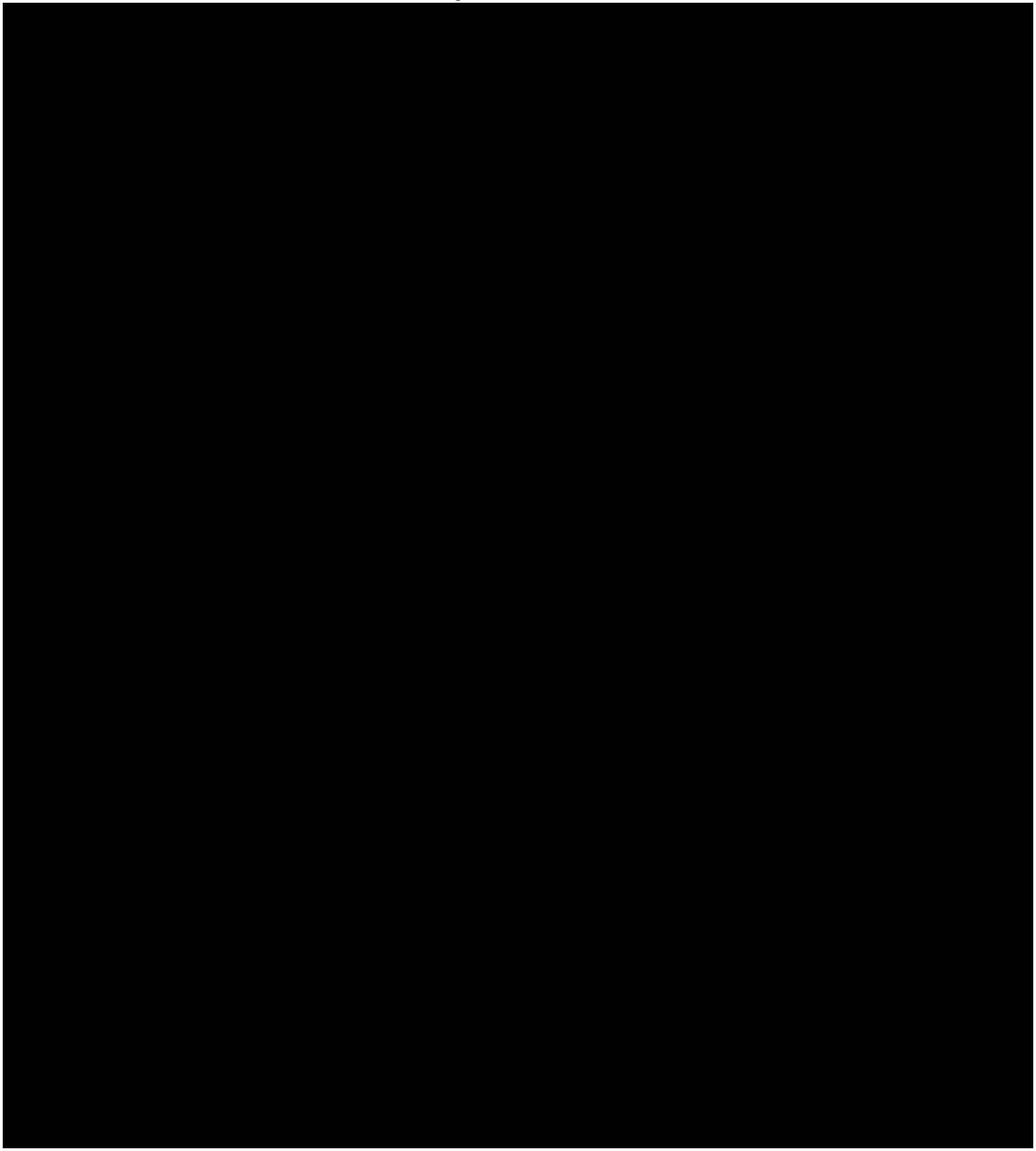

Exhibit C-10

Regression Results: Professor Cutler's Direct Model, 1999-2001 to 2009-2010

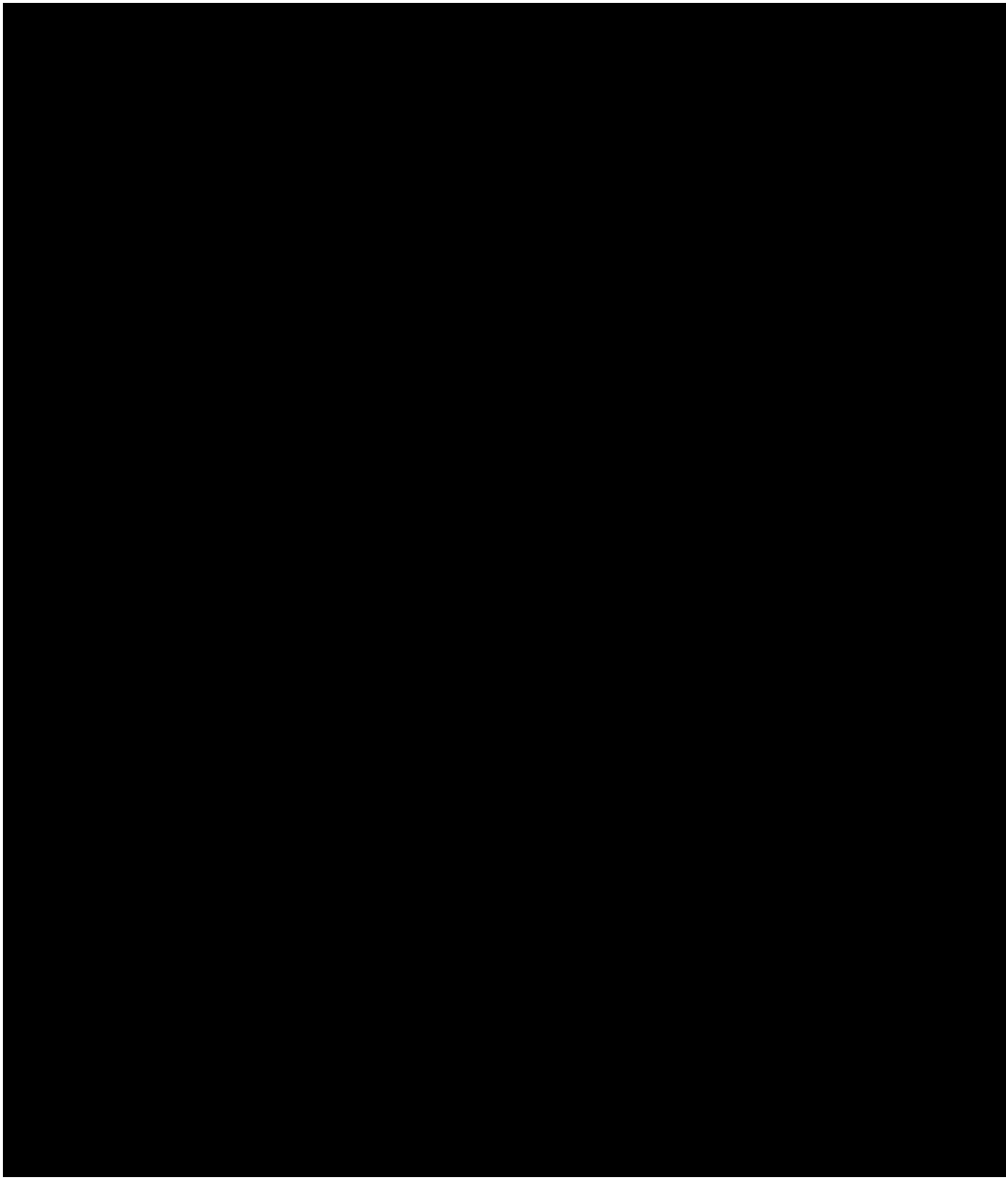

Exhibit C-11

Direct Model for Opioid Mortality Rate from 1993-1995 to 2009-2010

Large Counties

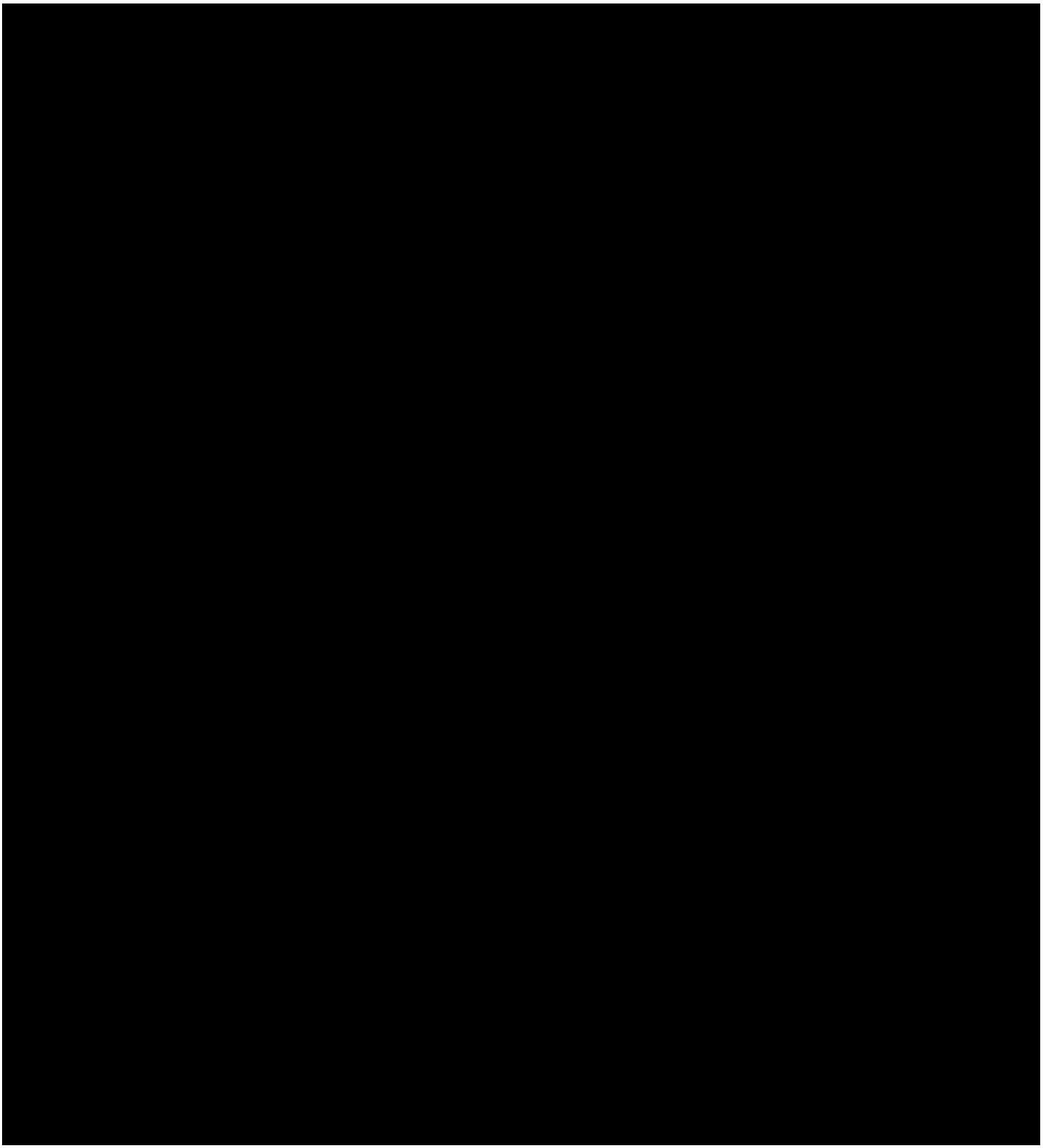

Exhibit C-12

Direct Model for Opioid Mortality Rate from 1993-1995 to 2009-2010

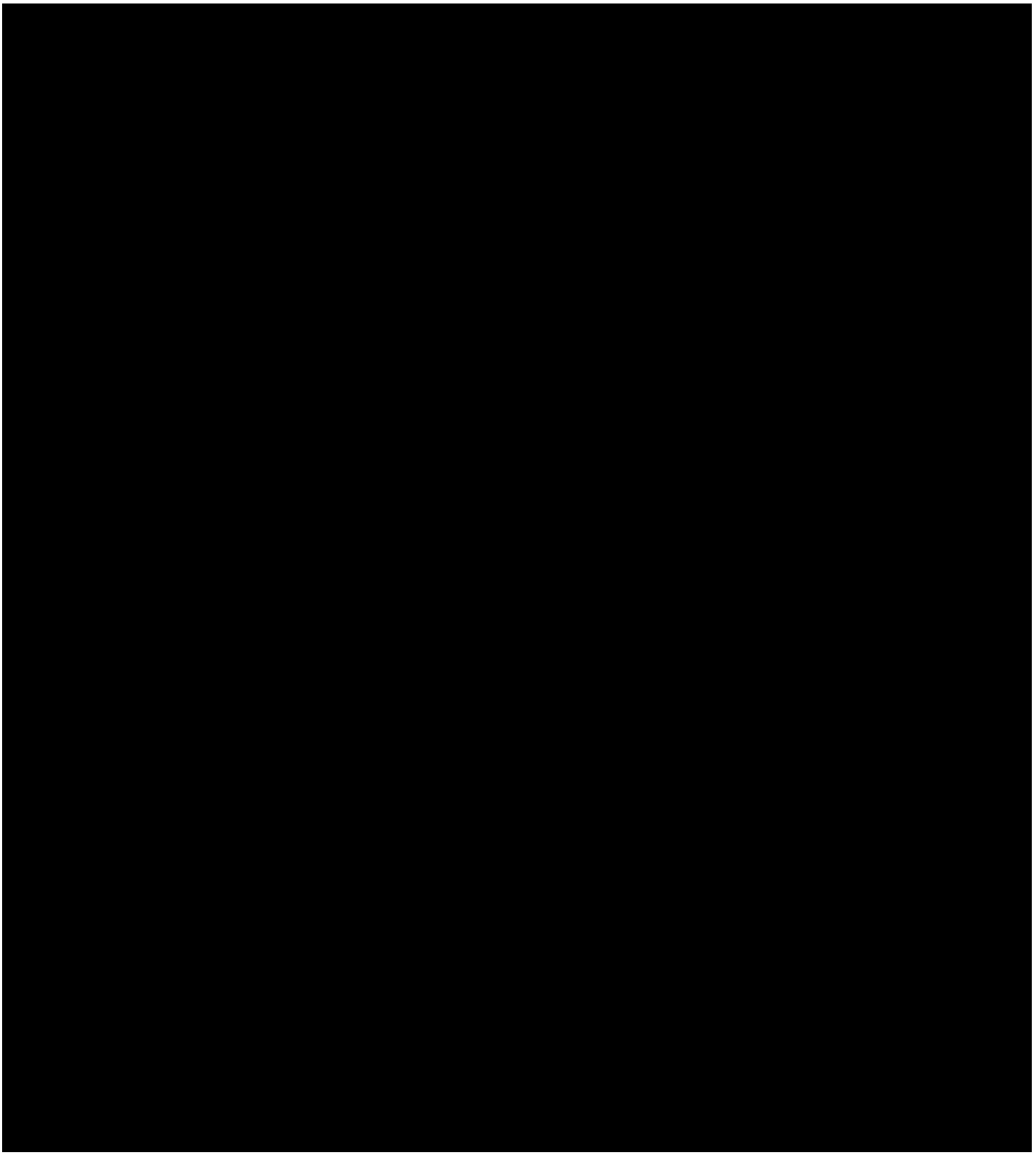

Exhibit C-13

Direct Model for Illicit Opioid Mortality Rate from 1999-2001 to 2015-2016

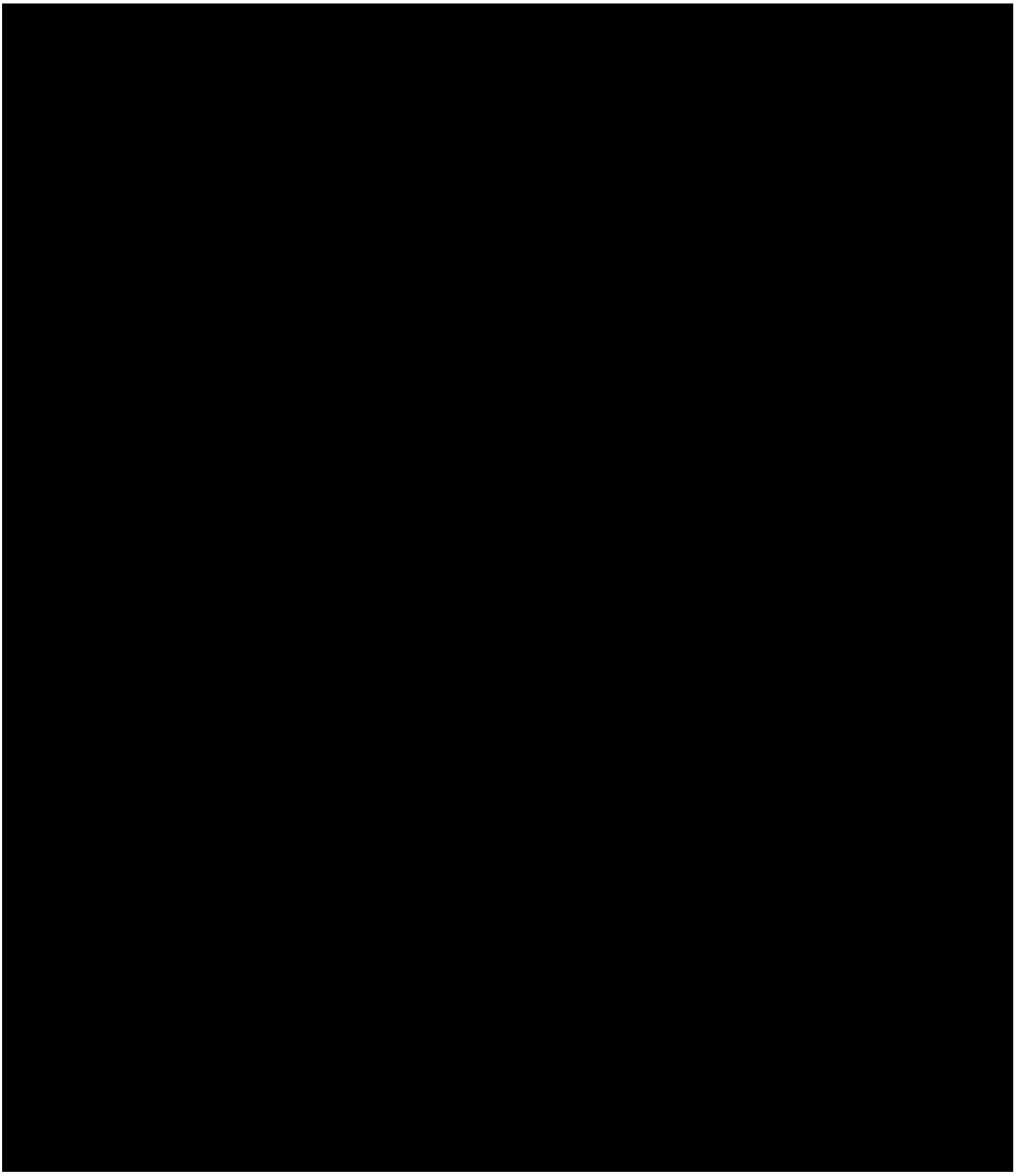

Exhibit C-14

Direct Model for Illicit Opioid Mortality Rate from 1999-2001 to 2010-2011

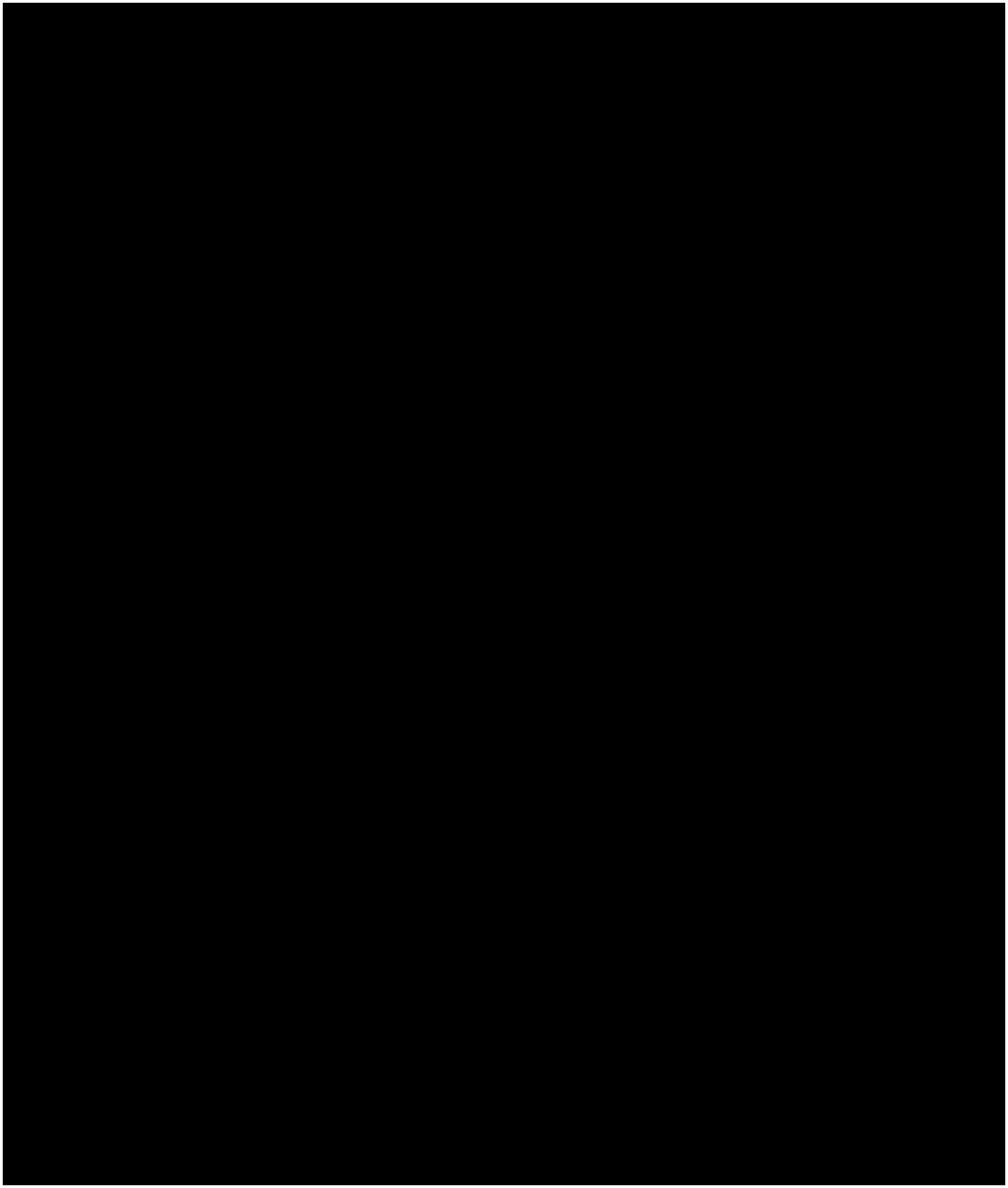

Exhibit C-15

Direct Model for Illicit Opioid Mortality Rate from 1999-2001 to 2011-2012

Large Counties

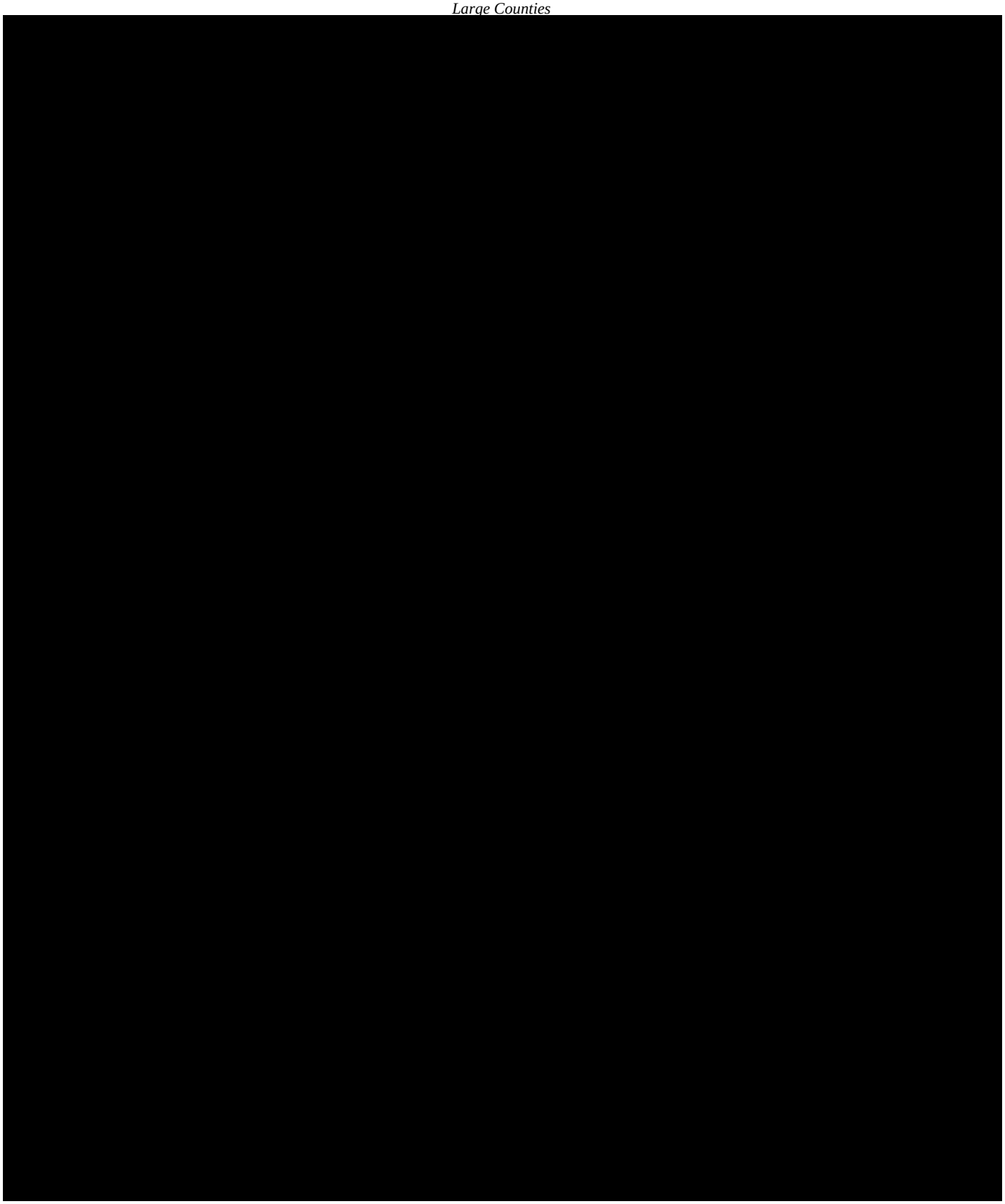

Exhibit C-16

Direct Model for Illicit Opioid Mortality Rate from 1999-2001 to 2012-2013

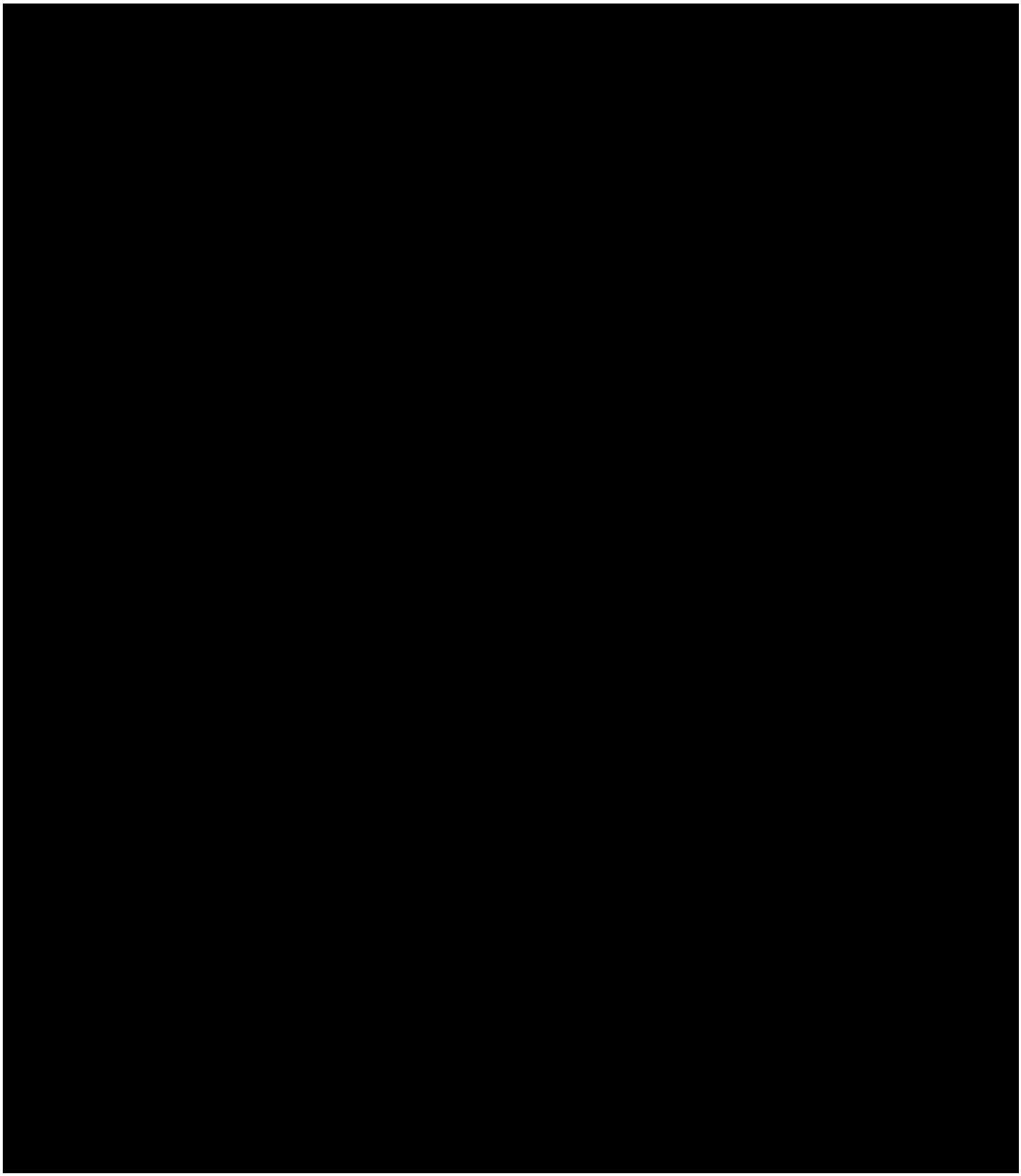

Exhibit C-17

Direct Model for Illicit Opioid Mortality Rate from 1999-2001 to 2013-2014

Large Counties

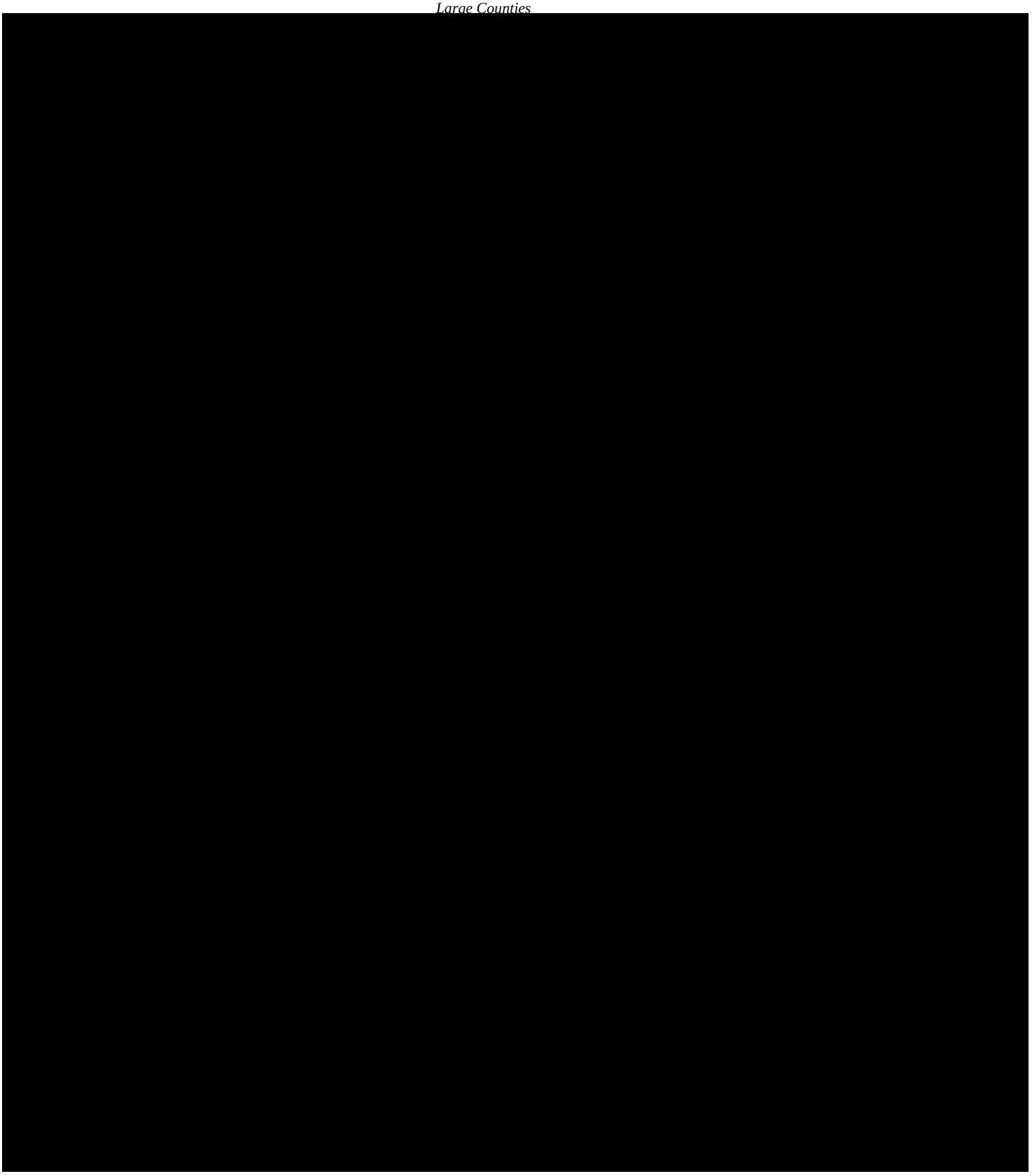

Exhibit C-18

Direct Model for Illicit Opioid Mortality Rate from 1999-2001 to 2014-2015

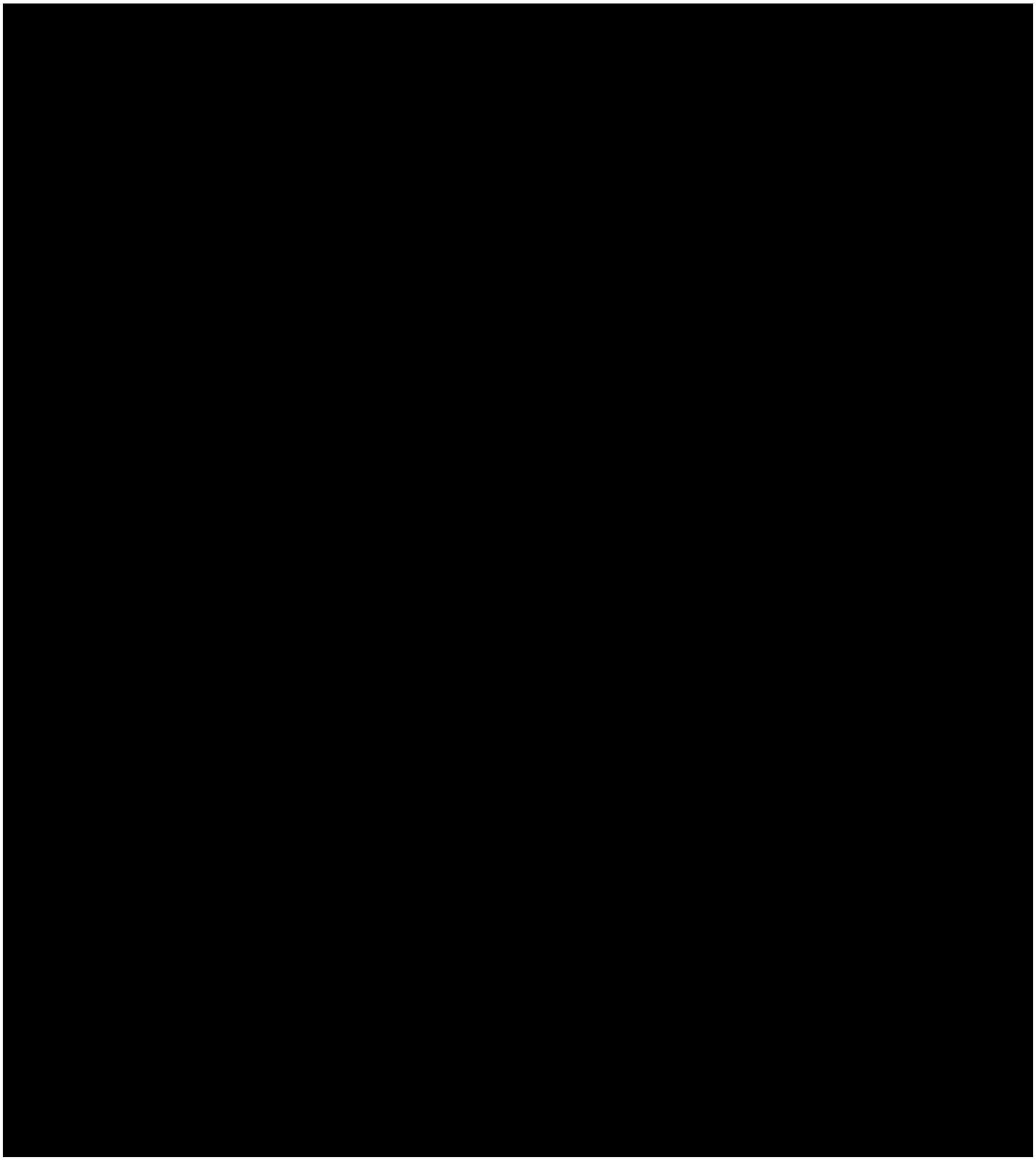

Exhibit C-19

Direct Model for Illicit Opioid Mortality Rate from 1999-2001 to 2015-2016

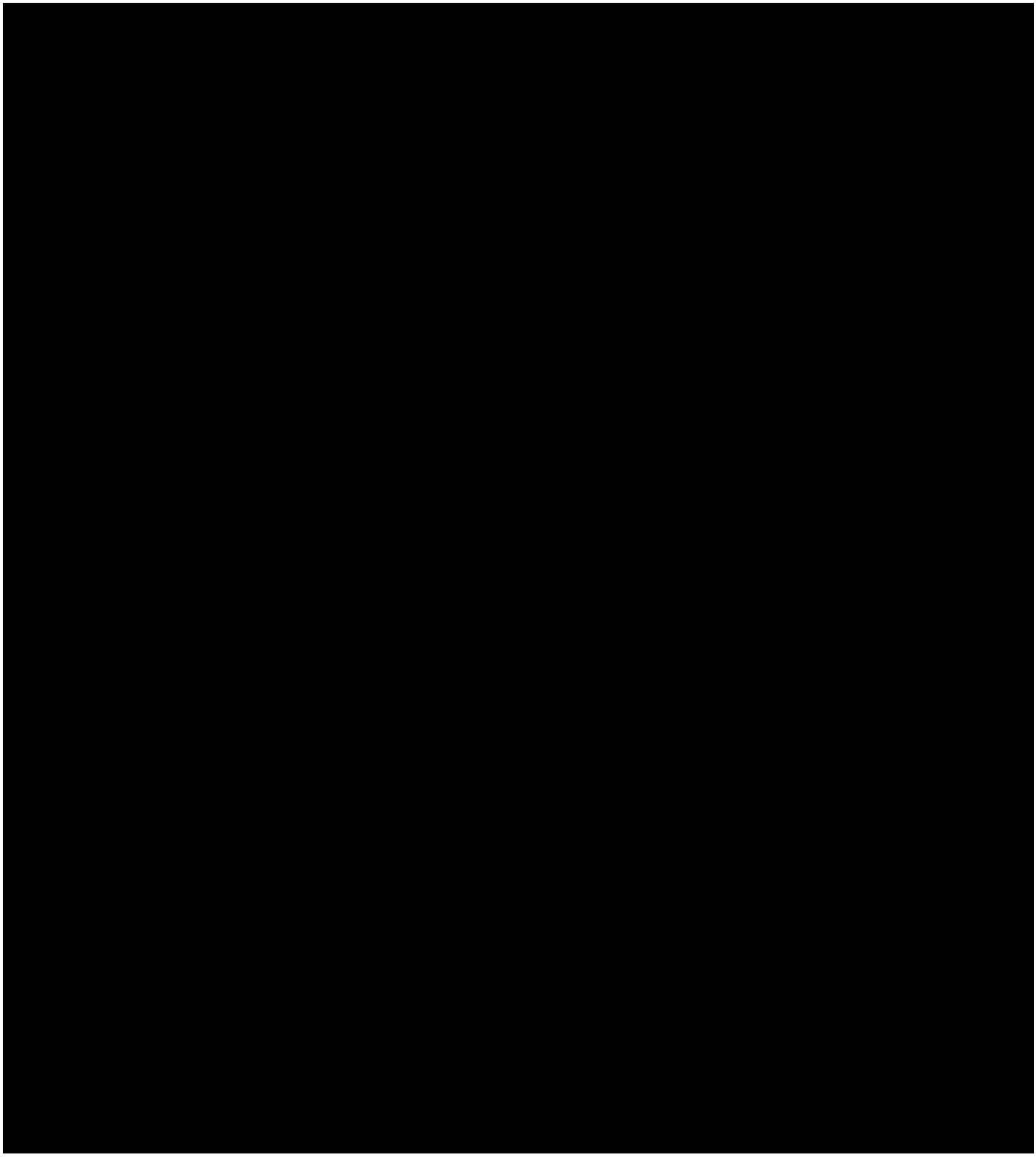

Exhibit C-20

Applying Professor Cutler's Methodology to Wood County Produces Nonsensical Results

Any Opioid	Licit (Rx + Methadone)

Exhibit C-21

Regression Results: Analysis of Property Crime Controlling for Non-Opioid Deaths of Despair, Method 1

Large Counties

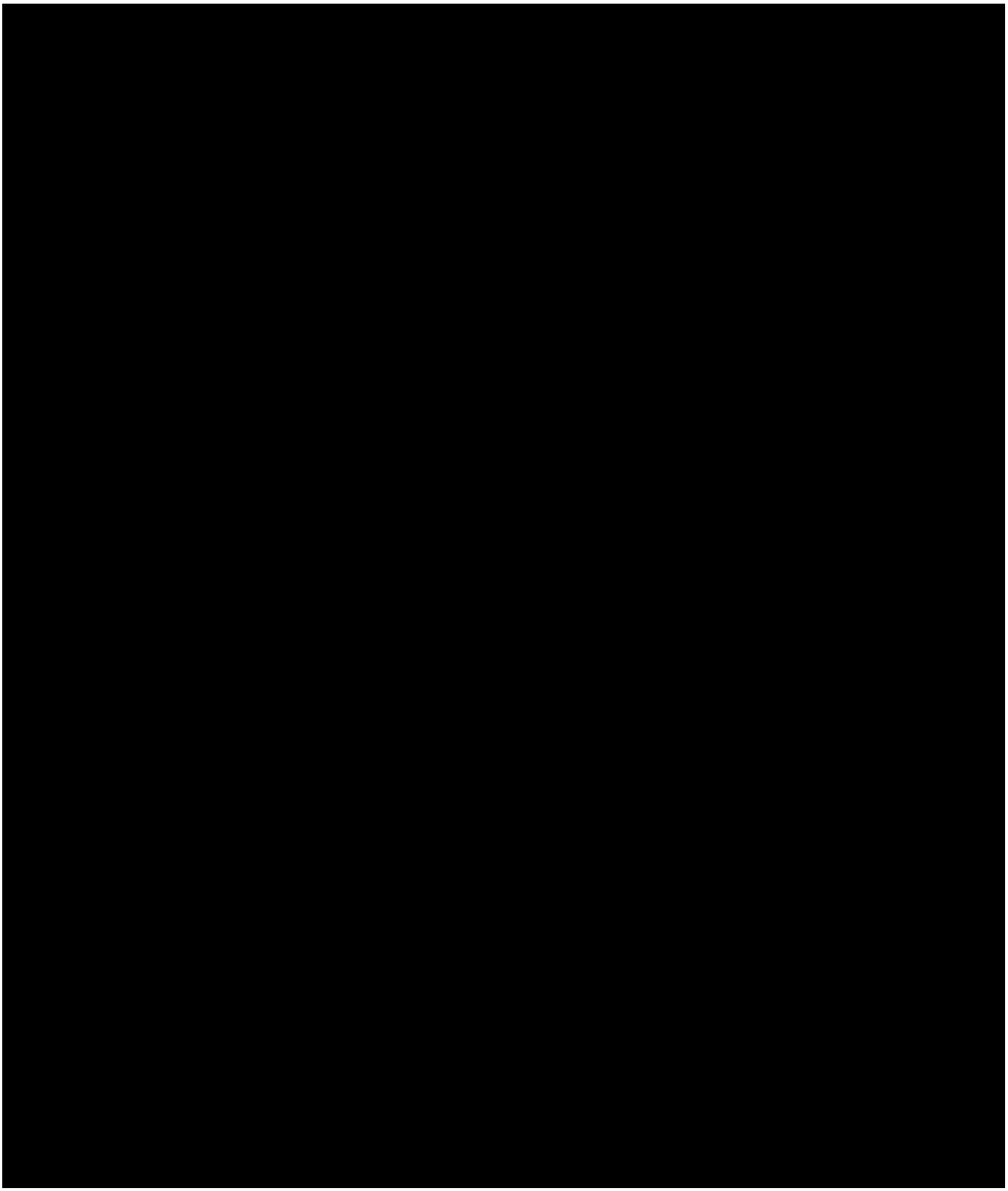

Exhibit C-22

Regression Results: Analysis of Property Crime Controlling for Non-Opioid Deaths of Despair, Method 2

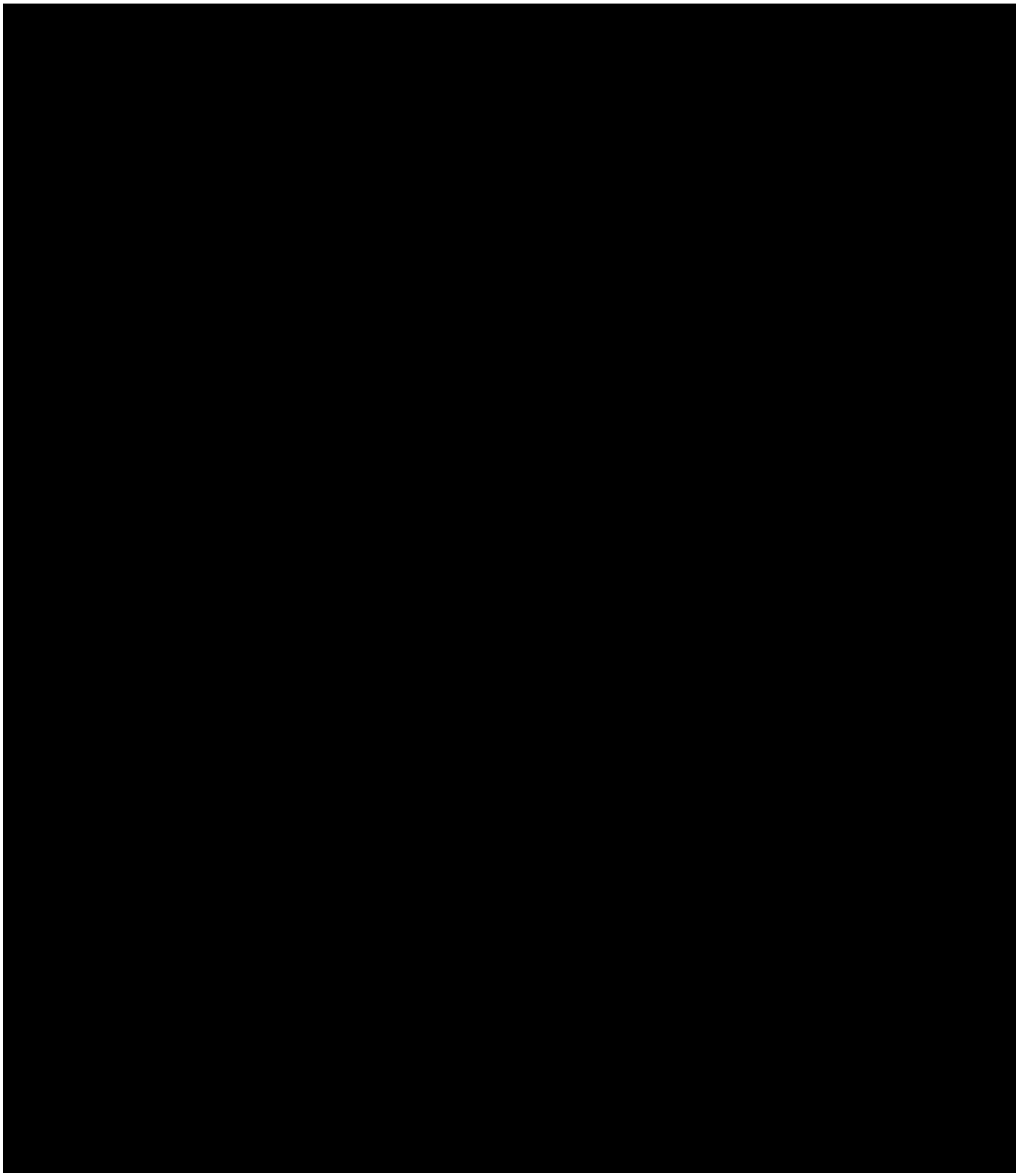

Exhibit C-23

Regression Results: Professor Cutler's Direct Model, 1999-2001 to 2009-2010, 343 Counties

Large Counties

[redacted]

Exhibit C-24

Regression Results: Professor Cutler's Direct Model, 1999-2001 to 2009-2010, 343 Counties

Large Counties

[redacted]

Exhibit C-25

Regression Results: Analysis of Violent Crime Controlling for Non-Opioid Deaths of Despair, Method 1

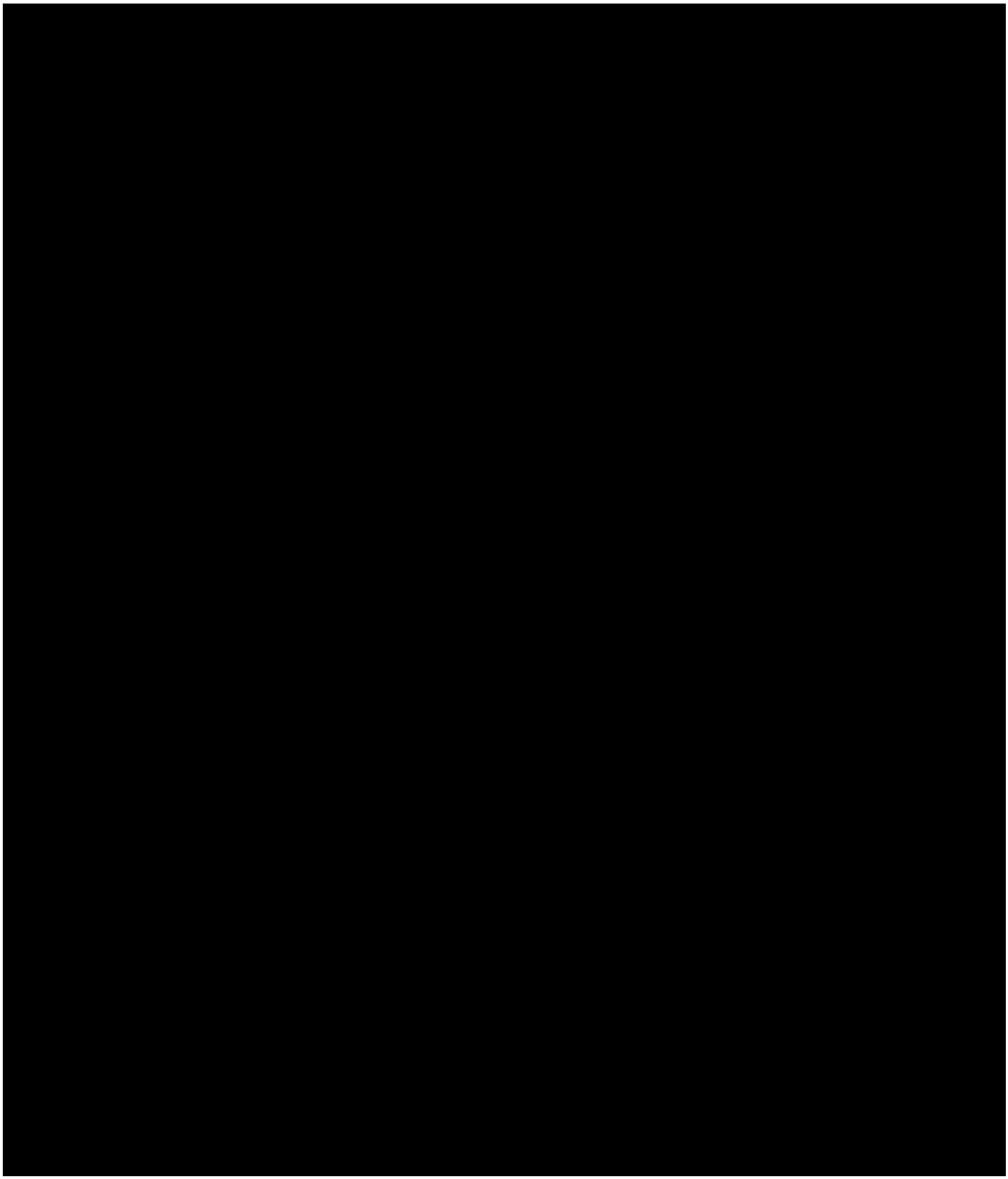

Exhibit C-26

Regression Results: Analysis of Violent Crime Controlling for Non-Opioid Deaths of Despair, Method 2

Large Counties

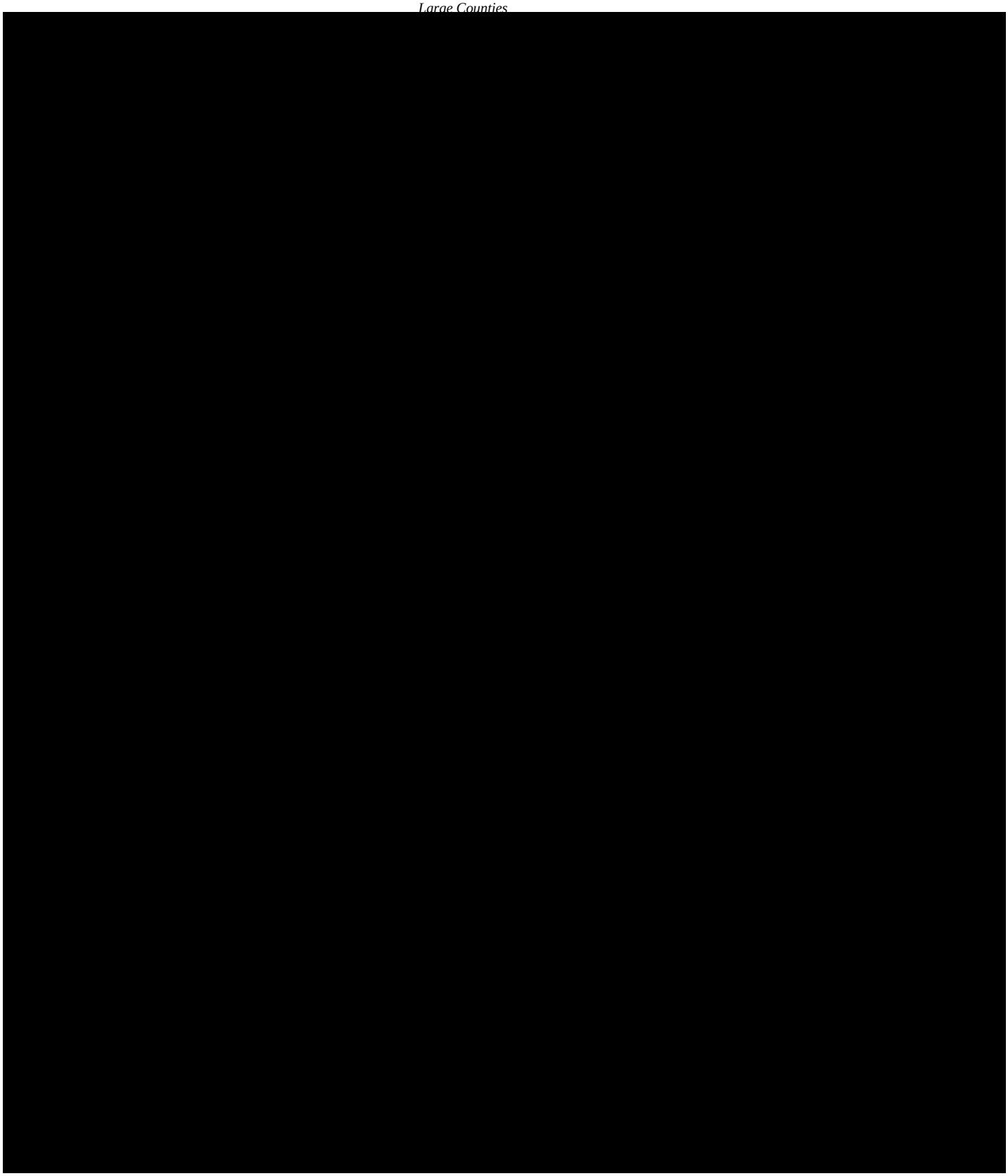

Exhibit C-27

Regression Results: Professor Cutler's Direct Model, 1999-2001 to 2009-2010, 343 Counties

[redacted]

Exhibit C-28

Regression Results: Professor Cutler's Direct Model, 1999-2001 to 2009-2010, 343 Counties

Large Counties